

Oncology, Immunology, Metabolic, Neurology

Effect-Size Predictions

Using Data-free Virtual Clinical Trials

96% accuracy

across 552 Oncology, Immunology, Metabolic,
Neurology trials

Overall: 96% across all 604 validated trials



 BioinvestGPT

Evidence Dossier

April 8, 2026

Platform Credentials at a Glance

96%

Prospective Prediction Accuracy

Across 552 validated trials (of 604 total) | Two-sided $p < 0.0001$

EA

100% Ex-Ante
Every prediction certified and sent to clients before trial results were known

RG

Industrial Rigor
Validated against real FDA/EMA clinical readouts

EP

Empirical Certainty
Statistically significant with two-sided $p < 0.0001$

Data-Free
Zero-Patient Input

White-Box
Root Cause Explained

Head-to-Head
vs. Standard of Care

552 of 604
Two-Sided $p < 0.0001$ ● LIVE

STRATEGIC VALUE PILLARS

Zero-Data Advantage

NO DATA SHARING
Predictions require **zero proprietary patient data**, eliminating **IP liability** and privacy friction.

2M VIRTUAL PATIENTS
Pre-built, **clinically validated** virtual cohorts delivering rigorous **effect-size predictions** across all major indications.

Eliminating Blind Spots

SURROGATE DETECTION
Simultaneously predicts early surrogates (**ORR/PFS**) and final efficacy (**OS**) to expose **hidden discordances**.

FUTURE-PROOFING
Benchmarks against **competitor** pipeline drugs to ensure **superiority at launch**, not just at trial start.

Identify Biological Root Cause

BEYOND BLACK-BOX
Every prediction is backed by **biological root cause identification**, not opaque probability scores.

ACTIONABLE DRIVERS
Pinpoints specific **failure/success drivers: target selection, drug design, delivery method, or patient stratification**.

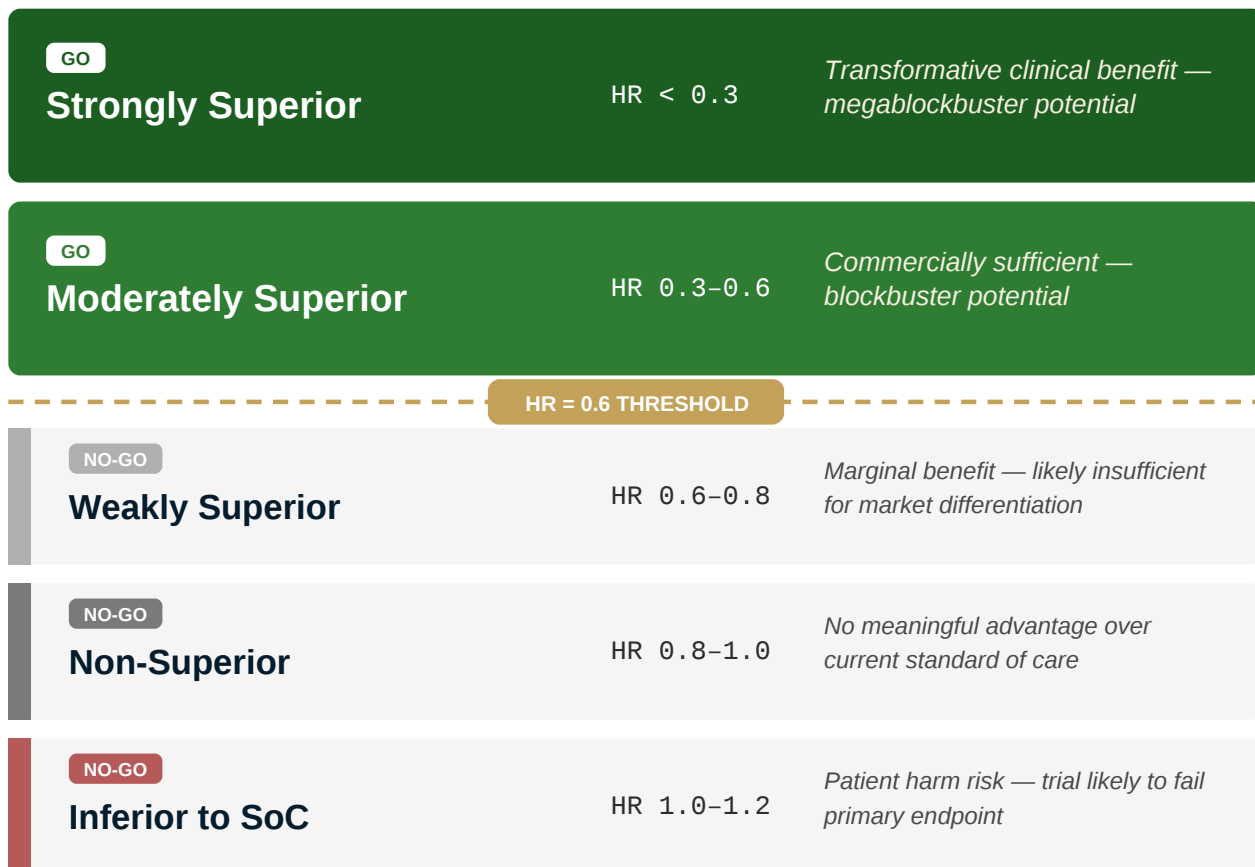


Effect-Size Portfolio Gating Spectrum

Oncology, Immunology, Metabolic, Neurology

552 of 604 validated trials

HAZARD RATIO GO/NO-GO THRESHOLD SPECTRUM



Configurable Threshold

Clients may select any HR value as the GO/NO-GO boundary based on their commercial case. We use HR = 0.6 as the default threshold for effect-size GO/NO-GO prospective predictions. GO = commercially sufficient effect size; NO-GO = commercially insufficient. See Trial Detail pages for each ex-ante validated prediction.

EX-ANTE PREDICTION ACCURACY



Full dataset: 96.0% (604 trials) | Filtered: 96.2% (552 trials) | Delta: +0.2pp

Predictive Performance Intelligence

Oncology, Immunology, Metabolic, Neurology

552 prospectively validated GO/NO-GO predictions

– IMPAIRMENT NO-GO correct rate

Negative Predictive Value (NPV)

99%

340/344 NO-GO predictions validated
 $TN / (TN + FN)$

99% of BioinvestGPT NO-GO predictions are prospectively independently validated, signaling **cost savings** from lackluster drugs. A NO-GO signal reliably identifies commercially insufficient FIC/BIC assets before Phase III spend, **preventing impairment write-downs**.

++RELIABILITY GO/NO-GO correct rate

Accuracy

96%

531/552 validated prospective predictions
 $(TP + TN) / (TP + TN + FP + FN)$

96% of BioinvestGPT GO/NO-GO predictions are correct for any-stage FIC/BIC assets, **nearly 10 times higher** than the industry's current best level (5–10%). BioinvestGPT prospectively predicts both drug successes and failures with **near-perfect reliability**.

++REVENUE GO correct rate

Positive Predictive Value (PPV)

92%

191/208 GO predictions validated
 $TP / (TP + FP)$

92% of BioinvestGPT GO predictions are prospectively independently validated as commercially sufficient drugs. A GO signal identifies **blockbuster FIC/BIC assets** with high reliability, enabling **revenue-maximizing** portfolio predictions.

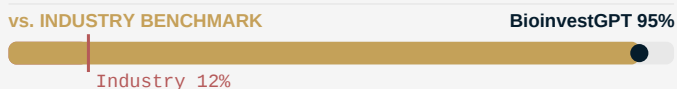
++RELIABILITY GO/NO-GO bias-free rate

F1-Score

95%

Harmonic mean of Precision and Recall
 $2 \times TP / (2 \times TP + FP + FN)$

Both GO and NO-GO predictions are almost **equally likely to be correct**, even though **blockbuster drugs are much rarer**. The model does not simply guess "failure" — it **makes the right call on both sides**.



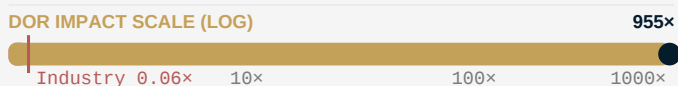
++RELIABILITY GO/NO-GO reliability rate

Diagnostic Odds Ratio (DOR)

955×

955× more likely correct than incorrect
 $(TP \times TN) / (FP \times FN)$

BioinvestGPT GO/NO-GO predictions is **955 times more likely to correctly identify blockbuster assets** (true positives) and **rule out commercially insufficient assets** (true negatives), compared with the chance of making an incorrect prediction.



* The F1-Score and DOR for current drug GO/NO-GO prospective prediction approach is estimated based on the industry 10% nomination rate (boehringer-ingelheim.com/science-innovation/human-health-innovation/drug-discovery).

Therapeutic Area Breakdown

Oncology, Immunology, Metabolic, Neurology

Exhibit 1

Prediction accuracy remains consistently high across all therapeutic domains

BioinvestGPT's validation dataset spans 4 major therapeutic areas, demonstrating that predictive accuracy is not an artifact of concentration in any single domain.



1. Source: BioinvestGPT validated prediction database. Classification based on clinical readout outcomes.
2. Therapeutic area mapping uses standardized groupings across 4 domains. Accuracy = (TP + TN) / Total.

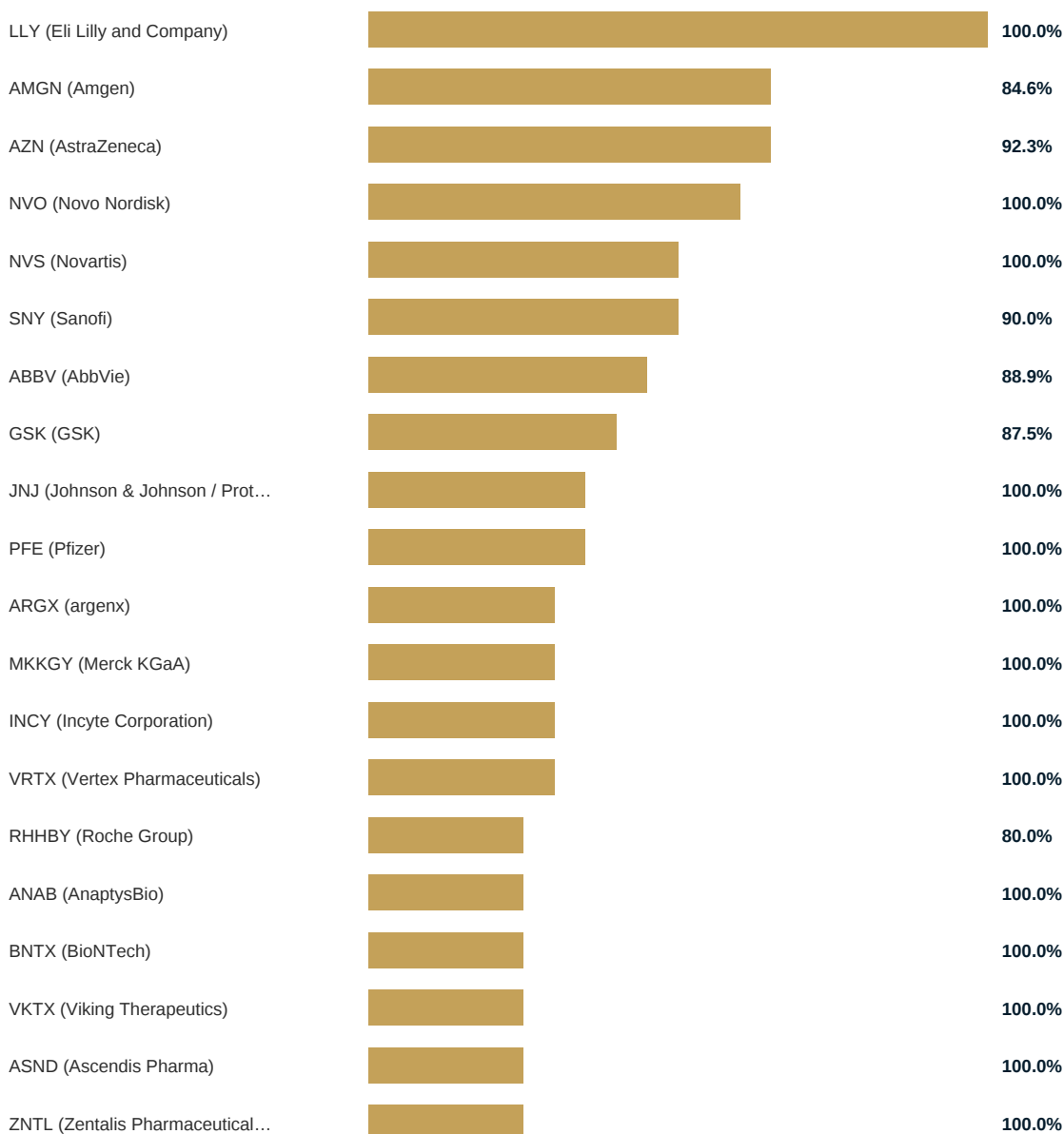
Sponsors Coverage Breakdown

Oncology, Immunology, Metabolic, Neurology

Exhibit 2

Validation spans 245 public biopharma sponsors across all market capitalizations

Coverage spans large-cap through small-cap sponsors, confirming model generalizability is not concentrated in any single company cohort.



Total unique sponsors: 245 | Average accuracy across top sponsors: 96.2%

1. Search sponsor name on data.bioinvestgpt.com to access the company-specific audited timestamped ex-ante predictions and readout validations.

Drug Innovation & Modality Coverage Breakdown

Oncology, Immunology, Metabolic, Neurology

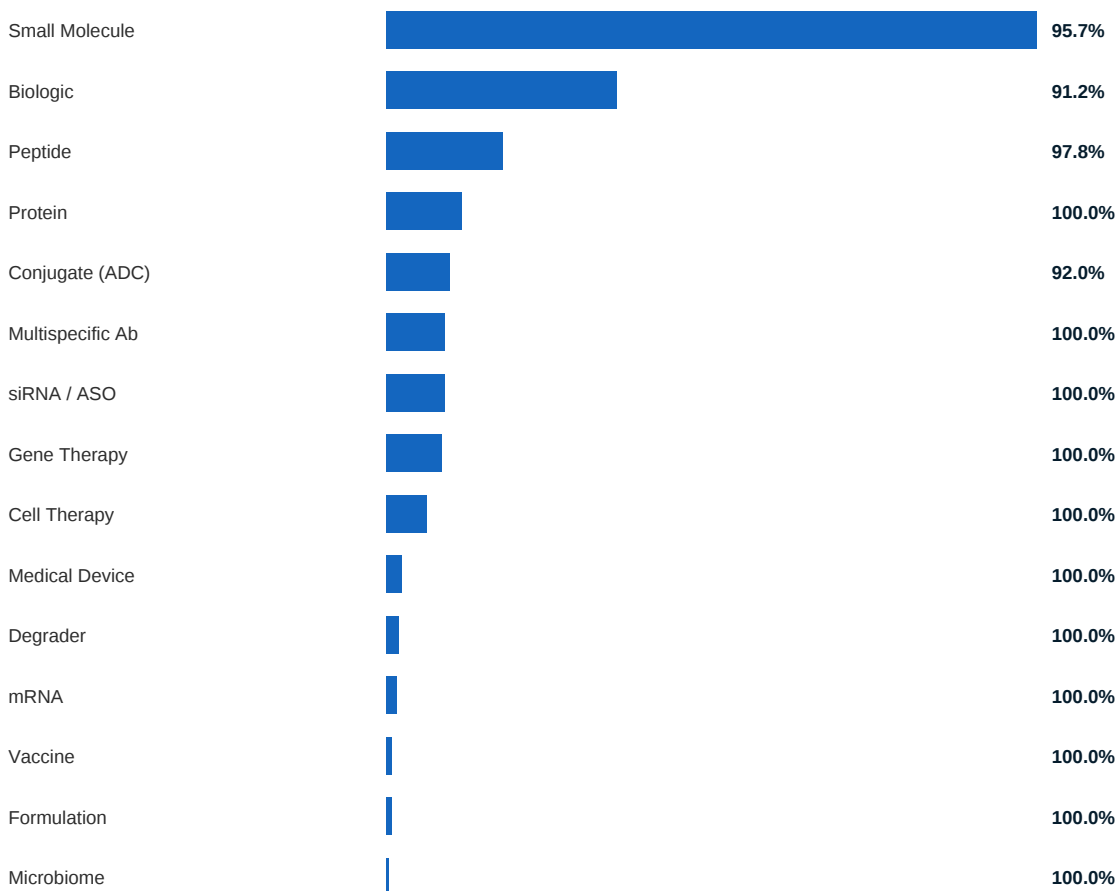
Exhibit 3

Validated across 446 distinct drug assets spanning 15 modalities

DRUG CLASSIFICATION



DRUG MODALITY DISTRIBUTION



Drug Assets Coverage Breakdown

Oncology, Immunology, Metabolic, Neurology

Exhibit 4

Validated across 446 distinct drug assets with consistently high prediction accuracy

Orforglipron		100.0%
Semaglutide		100.0%
Efgartigimod		100.0%
Tildacerfont		100.0%
icotrokinra (JNJ-2113)		100.0%
VK2735		100.0%
Evorpacept (ALX148)		100.0%
CagriSema		100.0%
Rocatinlimab		100.0%
GH001		100.0%
Imvotamab		100.0%
Lumateperone		100.0%
Tolebrutinib		100.0%
Izokibep		100.0%
ZN-c3		100.0%
ARO-APOC3		100.0%
Rosnilimab		100.0%
Bezuclastinib		100.0%
Upadacitinib		100.0%
Petosemtamab (MCLA-158)		100.0%
VTX3232		100.0%
Secukinumab		100.0%
Tiragolumab		100.0%

Total unique drug assets: 446 | Average accuracy across top drugs: 100.0%

1. Search drug name on data.bioinvestgpt.com to access the drug-specific audited timestamped ex-ante predictions and readout validations.

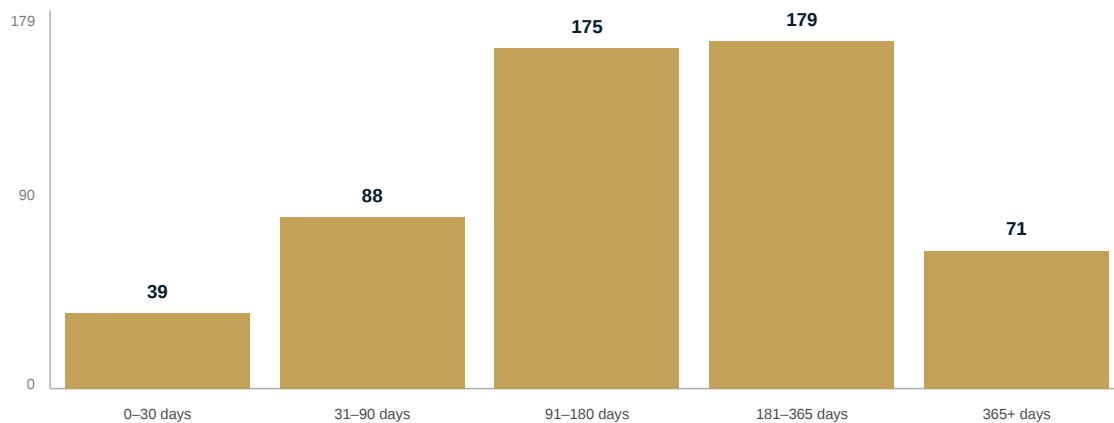
Temporal Integrity: Prospective Proof

Oncology, Immunology, Metabolic, Neurology

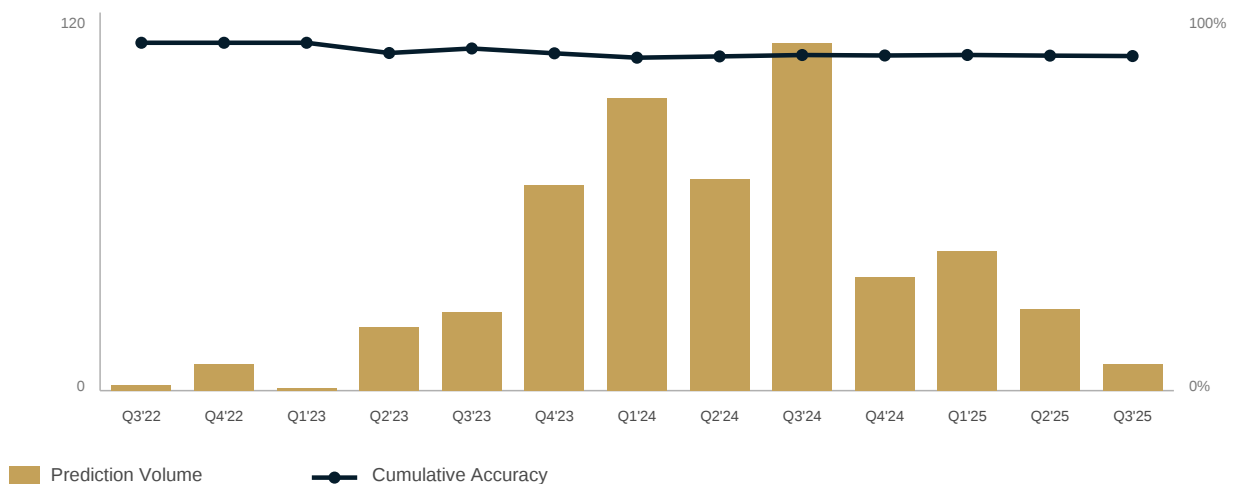
Exhibit 5

100% of predictions issued before clinical readout with median lead time of 202 days

LEAD TIME DISTRIBUTION



QUARTERLY PREDICTION VOLUME & CUMULATIVE ACCURACY



All 552 predictions were certified ex-ante, with an average lead time of 202 days before clinical readout. This temporal integrity is cryptographically verifiable and eliminates any possibility of post-hoc fitting.

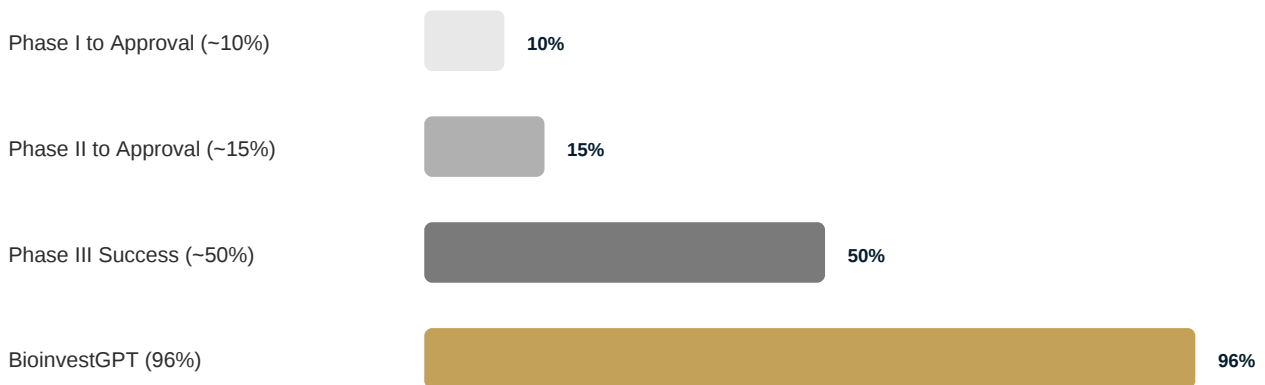
Competitive Benchmark Analysis

Oncology, Immunology, Metabolic, Neurology

Exhibit 6

BioinvestGPT demonstrates multi-order-of-magnitude improvement over industry baselines

CLINICAL DEVELOPMENT SUCCESS RATES



QUANTITATIVE BENCHMARK

Metric	BioinvestGPT	Industry Avg	Context
Accuracy	96.2%	~10-15%	Phase I-to-approval historical rate
Precision (PPV)	91.8%	~11%	Avg drug approval probability
NPV	98.8%	~60%	Combined Phase I-III attrition detection
F1-Score	94.8%	12%	Based on industry 10% nomination rate
DOR	955.0x	0.06x	Based on industry 10% nomination rate
Lead Time	202 days	0 days	Post-hoc industry standard

Note: Industry success rates measure population-level probability of a drug advancing through clinical development phases. BioinvestGPT predicts phase-agnostic effect-size-based clinical benefit using $HR = 0.6$ as the GO/NO-GO threshold to classify commercially sufficient vs. insufficient drugs, with all predictions certified ex-ante. The comparison illustrates the magnitude of predictive alpha, not a direct methodological equivalence.

REDIRECTABLE R&D CAPITAL

\$102.0B

340 of 344 NO-GO predictions validated × \$300M avg trial cost

CAPTURED PORTFOLIO VALUE

\$191.0B

191 of 208 GO predictions validated × \$1B avg revenue

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1756	Tolebrutinib NCTID: NCT04411641 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant BTK inhibitor Area: Nervous System Diseases Indication: Nonrelapsing Secondary Progressive Multiple Sclerosis (NRSPMS) Human Patients: 1131 Sponsor: Sanofi (SNY)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: FAILURE (statistically insignificant clinical benefit in 6-month CDP against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in 6-month CDP inferior to siponimod)	Readout: 24 Dec 2025 Lead Time: 492 days in advance Interpretation: tolebrutinib achieved 31% placebo-adjusted reduction in 6-month (CDP); non-superior to siponimod's 29-33% placebo-adjusted reduction in 6-month CDP in the EXPAND trial NCT01665144 (see add'l link below); FDA issued CRL rejecting Sanofi's NDA for tolebrutinib for NR-SPMS	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1957	Sotatercept NCTID: NCT04945460 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: ActRIIA/ACVR2A ligand trap Area: Cardiovascular Diseases Indication: combined post- and precapillary pulmonary hypertension (CpcPH) due to heart failure with preserved ejection fraction (HFpEF) Human Patients: 164 Sponsor: Merck & Co. (MRK)	Date: 1 Apr 2025 Quarter: Q2'25 Batch 14a Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in PVR/6MWD/LVEF compared with placebo as an adjunctive therapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in PVR/6MWD/LVEF inferior to semaglutide as an adjunctive therapy)	Readout: 18 Nov 2025 Lead Time: 231 days in advance Interpretation: sotatercept achieved statistical significance in PVR compared with placebo at week 24 (no detailed data and no p-value); yet sotatercept probably didn't achieve statistical significance in 6MWD (not mentioned; no detailed data and no p-value)	Correct Prediction Conclusion: statistically partially significant (weak efficacy in PVR but not 6MWD) and commercially probably insufficient Classification: True Negative (TN)
590	Zanidatamab NCTID: NCT05152147 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: biparatopic anti-HER2 inhibitor Area: Neoplasms Indication: 1L HER2-positive Advanced or Metastatic Gastric and Esophageal Cancers Human Patients: 920 Sponsor: Jazz Pharmaceuticals (JAZZ)	Date: 19 Jan 2025 Quarter: Q2'25 Batch 3 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy]) Commercial: SUCCESS (commercially sufficient clinical benefit in OS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy])	Readout: 17 Nov 2025 Lead Time: 302 days in advance Interpretation: zanidatamab + tislelizumab + chemotherapy achieved superiority in both PFS and OS compared with the control arm trastuzumab plus chemotherapy; whereas zanidatamab + chemotherapy achieved superiority in PFS only (not in OS) compared with the control arm trastuzumab plus chemotherapy	Correct Prediction Conclusion: statistically significant (superior PFS for both doublet and triplet combo therapies) and commercially sufficient (superior OS for triplet combo therapy) Classification: True Positive (TP)
1909	Alixorexton (ALKS2680) NCTID: NCT06555783 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: OX2R agonist Area: Nervous System Diseases Indication: Narcolepsy Type 2 Human Patients: 80 Sponsor: Alkermes (ALKS)	Date: 8 Feb 2025 Quarter: Q2'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in MWT for NT2 compared with placebo featuring a mild positive dose-response relationship and a moderate positive dose-toxicity relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in MWT for NT2; non-inferior non-superior to ALKS2680/TAK861 in the best-case scenarios of optimal dosing regimens)	Readout: 12 Nov 2025 Lead Time: 277 days in advance Interpretation: Alixorexton 14mg/18mg met the primary endpoint in MSL on MWT at week 8 (p<0.05) and Alixorexton 18mg met the key secondary endpoint in ESS (p<0.05)	Correct Prediction Conclusion: statistically significant (featuring a mild positive dose-response relationship) and commercially sufficient (no approved treatment so far) Classification: True Positive (TP)
2023	KRRO-110 NCTID: NCT06677307 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: oligonucleotide MoA: LNP-encapsulated ADAR-dependent mRNA single-base modifier	Date: 14 May 2025 Quarter: Q3'25 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in lung AAT/NE concentration compared with placebo) Commercial: FAILURE (commercially	Readout: 12 Nov 2025 Lead Time: 182 days in advance Interpretation: KRRO110 produced functional protein that hasn't reached the projected level; so further development has been discontinued for low efficacy	Correct Prediction Conclusion: statistically probably significant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Alpha-1 Antitrypsin Deficiency (AATD) Human Patients: 64 Sponsor: Korro Bio (KRRO)	insufficient clinical benefit in FEV1 moderately inferior to WVE006)		
2048	Fenebrutinib NCTID: NCT04544449 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant BTK inhibitor Area: Nervous System Diseases Indication: Primary Progressive Multiple Sclerosis Human Patients: 985 Sponsor: Roche Group (RHHBY)	Date: 28 Jul 2025 Quarter: Q4'25 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit in 12-week CDP compared with placebo) Commercial: SUCCESS (commercially sufficient yet moderate clinical benefit in 12-week CDP moderately superior to ocrelizumab)	Readout: 10 Nov 2025 Lead Time: 105 days in advance Interpretation: fenebrutinib met the primary endpoint of delay in the onset of composite confirmed disability progression over a period of at least 120 weeks of treatment; being numerically superior to ocrelizumab	Correct Prediction Conclusion: statistically significant and commercially sufficient (ocrelizumab is the only SoC) Classification: True Positive (TP)
1389	Rosnilimab NCTID: NCT06127043 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-PD1 agonist Area: Immune System Diseases Indication: Moderate to Severe Ulcerative Colitis Human Patients: 132 Sponsor: AnaptysBio (ANAB)	Date: 28 Jul 2025 Quarter: Q4'25 Batch 5 Technical: FAILURE (statistically insignificant clinical benefit in modified Mayo score or clinical remission compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in modified Mayo score or clinical remission moderately inferior to tolosikibart)	Readout: 10 Nov 2025 Lead Time: 105 days in advance Interpretation: rosnilimab failed to meet the primary efficacy endpoint of modified Mayo Score (mMS) compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
782	Bezuclastinib NCTID: NCT05208047 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: TKI inhibitor Area: Neoplasms Indication: Gastrointestinal Stromal Tumors (GIST) Human Patients: 442 Sponsor: Cogent Biosciences (COGT)	Date: 13 Oct 2023 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 10 Nov 2025 Lead Time: 759 days in advance Interpretation: bezuclastinib + sunitinib achieved 16.5 months mPFS vs 9.2 months mPFS achieved by sunitinib mono therapy (p<0.0001); bezuclastinib+sunitinib achieved 46% ORR vs 26% ORR achieved by sunitinib mono therapy (p<0.0001); wait for OS data	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially TBD Classification: True Positive (TP)
1662	NBI-1070770 NCTID: NCT06267846 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: oral anti-NMDAR-NR2B NAM Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 73 Sponsor: Neurocrine Biosciences (NBIX)	Date: 6 Jul 2024 Quarter: Q3'25 Batch 10 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in MADRS) Commercial: FAILURE (commercially insufficient additive clinical benefit in MADRS inferior to lumateperone)	Readout: 10 Nov 2025 Lead Time: 492 days in advance Interpretation: NBI-1070770 failed to meet the primary efficacy endpoint of MADRS compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1138	Suvecaltamide NCTID: NCT05642442 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: t-type calcium channel antagonist	Date: 21 Nov 2023 Quarter: Q2'25 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 6 Nov 2025 Lead Time: 716 days in advance Interpretation: suvecaltamide failed to meet the primary efficacy endpoint of TETRAS composite outcome score compared with placebo (P=0.2363)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Nervous System Diseases Indication: Moderate to Severe Residual Tremor in Parkinson's Disease Human Patients: 169 Sponsor: Jazz Pharmaceuticals (JAZZ)			
1887	Tegoprubart NCTID: NCT05983770 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CD40L inhibitor Area: Immune System Diseases Indication: Prevention of rejection in kidney transplantation Human Patients: 127 Sponsor: Eledon Pharmaceuticals (ELDN)	Date: 26 Jan 2025 Quarter: Q4'25 Batch 3 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in eGFR at most numerically superior to tacrolimus featuring negative dose-response relationship) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in eGFR/graft survival/BPAR at most numerically superior to tacrolimus)	Readout: 6 Nov 2025 Lead Time: 284 days in advance Interpretation: tegoprubart + SoC failed to achieve superiority in eGFR compared with tacrolimus + SoC	Correct Prediction Conclusion: statistically insignificant and commercially probably insufficient Classification: True Negative (TN)
1907	ORX750 NCTID: NCT06752668 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: OX2R agonist Area: Nervous System Diseases Indication: Narcolepsy and Idiopathic Hypersomnia Human Patients: 96 Sponsor: Centessa Pharmaceuticals (CNTA)	Date: 8 Feb 2025 Quarter: Q2'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in MWT for NT1 NT2 and IH compared with placebo; featuring a differential positive dose-response relationship (NT1 >> IH > NT2) and a differential positive dose-toxicity relationship (NT2 > IH)) Commercial: SUCCESS (commercially sufficient clinical benefit in MWT for NT1 NT2 and IH in observance of differential therapeutic windows (narrow range of high dose for NT2 medium range of medium dose for IH broad range of low dosage for NT1); non-superior to ALKS2680/TAK861 in the best-case scenarios of optimal dosing regimens)	Readout: 5 Nov 2025 Lead Time: 270 days in advance Interpretation: ORX750 1.5mg for NT1 achieved a >20 minute change from baseline in mean sleep latency compared with placebo on the MWT at Week 2 (p=0.0026). ORX750 4mg for NT2 achieved a >10 minute change from baseline in mean sleep latency compared with placebo on the MWT at Week 2 (p=0.0193). ORX750 2mg for IH achieved placebo-adjusted improvement in mean sleep latency compared with placebo on the MWT at Week 2 (p=0.0213)	Correct Prediction Conclusion: statistically significant (stronger efficacy in NT1 than in NT2/IH) and commercially probably sufficient Classification: True Positive (TP)
1853	Bemarituzumab NCTID: NCT05111626 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: FGFR2B inhibitor Area: Neoplasms Indication: 1L advanced gastric cancer/ GEJ cancer with FGFR2b over expression Human Patients: 515 Sponsor: Amgen (AMGN)	Date: 4 Dec 2024 Quarter: Q1'25 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to nivolumab + chemotherapy) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to nivolumab + chemotherapy)	Readout: 4 Nov 2025 Lead Time: 335 days in advance Interpretation: bemarituzumab + chemotherapy + nivolumab failed to deliver sufficient efficacy in PFS/ORR and further development has been discontinued	Missed Prediction Note: due to suboptimal modeling of drug MoA for ORR/PFS that has been permanently improved Conclusion: statistically insignificant (ORR/PFS) and commercially maybe sufficient (OS) Classification: False Positive (FP)
1697	TERN-701 NCTID: NCT06163430 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: BCR ABL1 myristoyl-pocket-binding TKI inhibitor Area: Neoplasms Indication: Relapsed/refractory Chronic Myeloid Leukemia Human Patients: 100	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: SUCCESS (statistically significant clinical benefit in CR) Commercial: partial SUCCESS (commercially sufficient clinical benefit in CR non-superior non-inferior to ELVN001 for CML patients without T315I mutation) partial FAILURE (commercially insufficient clinical benefit in CR)	Readout: 3 Nov 2025 Lead Time: 467 days in advance Interpretation: TERN701 achieved 64% MMR at week 24	Correct Prediction Conclusion: statistically probably significant and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Terns Pharmaceuticals (TERN)	inferior to ELVN001 for CML patients with either T315I mutation or asciminib intolerance)		
1301	INKmune NCTID: NCT06056791 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: NK cell activator Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer (mCRPC) Human Patients: 30 Sponsor: Immune Bio (INMB)	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 30 Oct 2025 Lead Time: 435 days in advance Interpretation: INKmune has met its primary endpoint and has not met the "reduction in tumour load" secondary endpoint	Correct Prediction Conclusion: statistically probably insignificant (ORR) and commercially probably insufficient Classification: True Negative (TN)
1971	Gefurulumab (ALXN1720) NCTID: NCT05556096 Phase: Phase 3 Class: First-In-Class Modality: bispecific nanobody MoA: bispecific nanobody that targets C5 and albumin Area: Immune System Diseases Indication: anti-acetylcholine receptor (AChR) antibody-positive (Ab+) generalized myasthenia gravis (gMG) Human Patients: 260 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: SUCCESS (statistically significant clinical benefit in MG-ADL and QMG compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in MG-ADL and QMG non-superior-non-inferior to efgartigimod)	Readout: 30 Oct 2025 Lead Time: 202 days in advance Interpretation: gefurulumab achieved -1.6 placebo-adjusted improvement in MG-ADL total score at week 26 (p<0.0001); non-superior-non-inferior to efgartigimod's 1.6-1.7 placebo-adjusted MG-ADL score reduction at week 8-11 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (non-superior-non-inferior to efgartigimod) Classification: True Negative (TN)
1938	Upadacitinib NCTID: NCT06118411 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: pan-JAK inhibitor with higher efficacy against JAK1 Area: Skin and Connective Tissue Diseases Indication: Vitiligo Human Patients: 614 Sponsor: AbbVie (ABBV)	Date: 24 Feb 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in F-VASI75/T-VASI50 for both upadacitinib monotherapy and upadacitinib + NB-UVB combotherapy compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit F-VASI75/T-VASI50 for both upadacitinib monotherapy and upadacitinib + NB-UVB combotherapy moderately superior to ruxolitinib)	Readout: 29 Oct 2025 Lead Time: 247 days in advance Interpretation: Upadacitinib 15mg achieved statistically significant 13.5%-15.6% placebo-adjusted T-VASI50 improvement at week 48 (p<0.05); statistically significant 16.5%-19.3% placebo-adjusted F-VASI75 improvement at week 48 (p<0.05); and statistically significant 30.5%-35.4% placebo-adjusted F-VASI50 improvement at week 48 (p value undisclosed); no clinical data for ruxolitinib in refractory vitiligo available	Correct Prediction Conclusion: statistically significant and commercially sufficient (no approved SoC for refractory vitiligo) Classification: True Positive (TP)
1642	Ianalumab (VAY736) NCTID: NCT05350072 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-BAFFR inhibitor Area: Immune System Diseases Indication: Sjögren Syndrome Human Patients: 276 Sponsor: Novartis Pharmaceuticals (NVS)	Date: 2 Jul 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit in ESSDAI as an adjunctive treatment to background therapies) Commercial: FAILURE (commercially insufficient additive clinical benefit inferior to iscalimab that's further inferior to rituximab in ESSDAI as an adjunctive treatment to background therapies)	Readout: 29 Oct 2025 Lead Time: 484 days in advance Interpretation: Ianalumab achieved -1.3 placebo-adjusted difference in ESSDAI score at week 48 (p=0.05); inferior to iscalimab 300mg that achieved -3.0 placebo-adjusted difference in ESSDAI score at week 24 (p=0.0090; see add'l link below)	Correct Prediction Conclusion: statistically borderline significant and commercially probably insufficient (inferior to iscalimab) Classification: True Negative (TN)
1150	Encaleret NCTID: NCT05680818 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CaSR antagonist	Date: 26 Jan 2025 Quarter: Q2'25 Batch 6 Technical: partial SUCCESS (statistically significant clinical benefit in cCa/24-hr UCa at most numerically superior to SoC yet with a negative	Readout: 29 Oct 2025 Lead Time: 276 days in advance Interpretation: encaleret achieved superiority in the primary endpoint of the proportion of participants achieving both normal cCa and	Correct Prediction Conclusion: statistically significant and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Endocrine System Diseases Indication: Autosomal Dominant Hypocalcemia Type 1 (ADH1) Human Patients: 67 Sponsor: BridgeBio Pharma (BBIO)	dose-response relationship) Commercial: partial FAILURE (commercially maybe sufficient yet very weak clinical benefit in QTcF/SF36 non-superior to SoC)	normal 24-hr UCa at week 24 compared with standard-of-care treatments (76% vs 4% p<0.0001); yet encalaret failed to achieve superiority in key efficacy endpoints such as QTcF or SF-36 (data not disclosed)	
1116	NTLA-2001 (nex-z) NCTID: NCT04601051 Phase: Phase 1 Class: First-In-Class Modality: gene therapy MoA: NP-delivered CRISPR-Cas9 reducing TTR production Area: Nervous System Diseases Indication: Patients With Hereditary Transthyretin Amyloidosis With Polyneuropathy (ATTRv-PN) and With Transthyretin Amyloidosis-Related Cardiomyopathy (ATTR-CM) Human Patients: 72 Sponsor: Intellia Therapeutics (NTLA)	Date: 23 Jul 2023 Quarter: 2H'23 Batch 11 Technical: partial FAILURE (statistically insignificant clinical benefit in 6MWT for cardiomyopathy or in 10MWT for polyneuropathy) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 27 Oct 2025 Lead Time: 827 days in advance Interpretation: nex-z phase 3 clinical trials in ATTR-CM (MAGNITUDE) and ATTR-PN (MAGNITUDE-2) have been paused due to grade 4 hepatotoxicity in a patient	Correct Prediction Conclusion: statistically insignificant and commercially probably insufficient Classification: True Negative (TN)
1890	BBP-418 (Ribitol) NCTID: NCT05775848 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: prodrug ribitol Area: Musculoskeletal Diseases Indication: Limb-Girdle Muscular Dystrophy Type 21 (LGMD2I) Human Patients: 81 Sponsor: BridgeBio Pharma (BBIO)	Date: 26 Jan 2025 Quarter: Q2'25 Batch 6 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in NSAD/10MWR compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in NSAD/10MWR non-superior to FKRP gene therapy)	Readout: 27 Oct 2025 Lead Time: 274 days in advance Interpretation: BBP418 achieved 0.27m/s placebo-adjusted improvement in 100MTT (p<0.0001); which is below the MCID threshold (>=0.55m/s placebo-adjusted improvement in 100MTT; calculated using the 112.2(127.9) baseline 100MTT of patients in the FORTIFY trial (see add'l link below) and the 1/3 SD MCID definition (doi.org/10.1212/WNL.92.15_supplement.S33.003)	Correct Prediction Conclusion: statistically significant yet weak clinical benefit and commercially probably insufficient Classification: True Negative (TN)
2024	Petosemtamab (MCLA-158) NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L/2L/3L metastatic colorectal cancer (mCRC) Human Patients: 523 Sponsor: Merus (MRUS)	Date: 16 May 2025 Quarter: Q3'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in PFS/ORR for petosemtamab monotherapy non-inferior to FTD-TPI + bevacizumab in the 3L MSS mCRC clinical setting) SUCCESS (statistically significant clinical benefit in PFS/ORR for petosemtamab + FOLFIRI/FOLFOX slightly-to-moderately superior to FOLFIRI/FOLFOX + bevacizumab in the 1L/2L MSS mCRC clinical setting) Commercial: SUCCESS (commercially sufficient clinical benefit in OS for petosemtamab monotherapy moderately-to-strongly superior to FTD-TPI + bevacizumab in the 3L MSS mCRC clinical setting) SUCCESS (commercially sufficient clinical benefit in OS for petosemtamab + FOLFIRI/FOLFOX moderately superior to FOLFIRI/FOLFOX + bevacizumab in the 1L/2L MSS mCRC clinical setting)	Readout: 24 Oct 2025 Lead Time: 161 days in advance Interpretation: Petosemtamab plus FOLFOX/FOLFIRI for 1L mCRC achieved 50-80% ORR (8/10 with 3 unconfirmed) slightly-to-moderately superior to 53% achieved by bevacizumab plus FOLFOX/FOLFIRI (see add'l link below); Petosemtamab plus FOLFOX/FOLFIRI for 2L mCRC achieved 46-62% cORR (6/13 with 2 unconfirmed) moderately-to-strongly superior to 11% achieved by bevacizumab plus FOLFOX/FOLFIRI (10.1093/annonc/mdv197); Petosemtamab mono therapy achieved 10% cORR (2/20) slightly superior to 6.1% cORR achieved by FTD-TPI plus bevacizumab (10.1056/NEJMoa2214963)	Correct Prediction Conclusion: statistically significant (superior-to-SoC ORR for 1L/2L/3L mCRC) and commercially TBD Classification: True Positive (TP)
2017	XmAb819 NCTID: NCT05433142 Phase: Phase 1	Date: 13 May 2025 Quarter: Q3'25 Batch 7 Technical: FAILURE (statistically	Readout: 24 Oct 2025 Lead Time: 164 days in advance Interpretation: XmAb819 achieved	Correct Prediction Conclusion: statistically probably insignificant (non-superior ORR)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody that binds both ENPP3 and CD3 Area: Neoplasms Indication: 2L+ advanced clear cell renal cell carcinoma (ccRCC) Human Patients: 95 Sponsor: Xencor (XNCR)	insignificant clinical benefit in ORR/PFS compared with placebo with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS strongly inferior to cabozantinib)	20% cORR (4/20) with 1 Grade 4 TEAE (5%); which is non-superior to the SoC cabozantinib that achieved 21% cORR (see add'l link below)	and commercially TBD Classification: True Negative (TN)
1906	VTX3232 NCTID: NCT06771115 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant NLRP3 inhibitor Area: Nutritional and Metabolic Diseases Indication: Obesity without type 2 diabetes Human Patients: 176 Sponsor: Ventyx Biosciences (VTYX)	Date: 8 Feb 2025 Quarter: Q2'25 Batch 9 Technical: FAILURE (statistically insignificant (additive) clinical benefit in weight loss compared with placebo despite moderate toxicity) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in weight loss/tolerability inferior to semaglutide monotherapy)	Readout: 22 Oct 2025 Lead Time: 256 days in advance Interpretation: VTX3232 failed to achieve statistical significance in weight reduction either as monotherapy or as add-on treatment to semaglutide	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1649	Secukinumab NCTID: NCT05767034 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-IL17A inhibitor Area: Immune System Diseases Indication: Polymyalgia Rheumatica (PMR) Human Patients: 381 Sponsor: Novartis Pharmaceuticals (NVS)	Date: 2 Jul 2024 Quarter: Q4'25 Batch 6 Technical: SUCCESS (statistically significant additive clinical benefit in sustained remission in combination with 24wk prednisone taper regimen; though secukinumab's additive efficacy for PMR would be smaller than that for GCA) Commercial: SUCCESS (commercially sufficient additive clinical benefit in sustained remission superior to tocilizumab in combination with 24wk prednisone taper regimen)	Readout: 22 Oct 2025 Lead Time: 477 days in advance Interpretation: Secukinumab + SoC met the primary endpoint and all secondary endpoints at week 52 compared with SoC alone	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
579	AL001 NCTID: NCT04374136 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-SORT1 inhibitor Area: Nervous System Diseases Indication: Frontotemporal Dementia due to a progranulin gene mutation (FTD-GRN) Human Patients: 110 Sponsor: Alecto (ALEC)	Date: 28 Jul 2025 Quarter: Q4'25 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit in CDR + NACC FTLD-SB compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in CDR + NACC FTLD-SB)	Readout: 21 Oct 2025 Lead Time: 85 days in advance Interpretation: AL001 failed to meet the primary endpoint of slowing FTD-GRN progression	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1945	Gedatolisib NCTID: NCT05501886 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: dual mTOR/PI3K inhibitor Area: Neoplasms Indication: PIK3CA WT and MT advanced or metastatic HR+/HER2- breast cancer Human Patients: 701 Sponsor: Celcuity (CELC)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 13a Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit in ORR/PFS for gedatolisib + fulvestrant + palbociclib moderately superior to SoC alpelisib + fulvestrant for PIK3CA MT population slightly superior to SoCfulvestrant for PIK3CA WT population despite with additional gedatolisib-related toxicity) partial FAILURE (statistically insignificant additive clinical benefit in ORR/PFS for gedatolisib + fulvestrant non-superior to SoC fulvestrant for both PIK3CA MT population and	Readout: 20 Oct 2025 Lead Time: 207 days in advance Interpretation: gedatolisib + palbociclib + fulvestrant ("gedatolisib triplet") achieved 9.3 months mPFS strongly superior to 2.0 months achieved by fulvestrant monotherapy (HR= 0.24; P<0.0001) yet achieved 23.7 months mOS only numerically superior to 18.5 months achieved by fulvestrant monotherapy (HR=0.69 P=0.1328); wait for MT population data	Correct Prediction Conclusion: statistically significant (superior mPFS) and commercially insufficient (non-superior mOS) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
		PIK3CA WT with additional gedatolisib-related toxicity) Commercial: partial FAILURE (commercially insufficient additive clinical benefit in OS for gedatolisib + fulvestrant + palbociclib at most numerically superior to SoC alpelisib + fulvestrant for PIK3CA MT population and non-superior to SoC fulvestrant for PIK3CA WT population despite with additional gedatolisib-related toxicity) FAILURE (commercially insufficient additive clinical benefit in OS for gedatolisib + fulvestrant non-inferior to SoC for both PIK3CA MT population PIK3CA WT population with additional gedatolisib-related toxicity)		
2011	Zanzalintinib NCTID: NCT05425940 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: multi-receptor TKI Area: Neoplasms Indication: 2L MSI-high Metastatic Colorectal Cancer Human Patients: 901 Sponsor: Exelixis (EXEL)	Date: 7 May 2025 Quarter: Q3'25 Batch 6 Technical: partial FAILURE (statistically maybe significant yet very weak clinical benefit for XL092 + atezolizumab in ORR/PFS at most numerically superior to regorafenib) Commercial: FAILURE (commercially insufficient clinical benefit for XL092 + atezolizumab in OS non-superior to regorafenib)	Readout: 20 Oct 2025 Lead Time: 166 days in advance Interpretation: zanzalintinib + atezolizumab achieved statistically significant yet very weak OS in the ITT population (HR = 0.8 p=0.0045) yet statistically insignificant OS in the subset of patients without liver metastases (p = 0.087); compared with the regorafenib mono therapy	Correct Prediction Conclusion: partially statistically significant and commercially insufficient Classification: True Negative (TN)
1786	Tiragolumab NCTID: NCT04513925 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-TIGIT inhibitor Area: Neoplasms Indication: Non-small Cell Lung Cancer (NSCLC) Human Patients: 829 Sponsor: Roche Group (RHHBY)	Date: 15 Sep 2024 Quarter: Q4'24 Batch 17b Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS numerically superior to durvalumab monotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to durvalumab monotherapy)	Readout: 18 Oct 2025 Lead Time: 398 days in advance Interpretation: tiragolumab + atezolizumab failed to achieve the primary endpoint non-superior to the SoC durvalumab in either mPFS (14.2 months vs 13.8 months) or OS (not reached vs 54.8 months)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1121	Ciforadenant NCTID: NCT05501054 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: adenosine A2a Receptor Antagonist Area: Neoplasms Indication: 1L metastatic renal cell cancer (RCC) Human Patients: 50 Sponsor: Corvus Pharmaceuticals (CRVS)	Date: 8 May 2025 Quarter: Q3'25 Batch 6 Technical: FAILURE (statistically insignificant additive clinical benefit to nivolumab + ipilimumab in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefitS to nivolumab + ipilimumab in OS)	Readout: 17 Oct 2025 Lead Time: 162 days in advance Interpretation: ciforadenant + ipilimumab + nivolumab achieved 46% ORR and 11 months mPFS; non-superior to ipilimumab + nivolumab that achieved 42% ORR and 11.6 months mPFS (see add'l link below); ciforadenant + ipilimumab + nivolumab achieved a numerical improvement of OS HR by 0.05 compared with ipilimumab + nivolumab (0.69 vs 0.74)	Correct Prediction Conclusion: statistically insignificant (non-superior ORR/PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1952	Orforglipron NCTID: NCT06109311 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Type 2 diabetes inadequately controlled with titrated insulin glargine; with or without metformin and/or SGLT-2 inhibitors	Date: 30 Mar 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in HbA1c and weight reduction compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction non-superior-non-inferior to semaglutide/GSBR1290 with	Readout: 15 Oct 2025 Lead Time: 199 days in advance Interpretation: orforglipron 36mg achieved 1.1% placebo-adjusted A1C reduction at week 40	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 546 Sponsor: Eli Lilly and Company (LLY)	numerically-inferior-to-semaglutide tolerability)		
1949	Orforglipron NCTID: NCT06192108 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Type 2 diabetes inadequately controlled on metformin Human Patients: 962 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in HbA1c and weight reduction compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction moderately superior to dapagliflozin)	Readout: 15 Oct 2025 Lead Time: 199 days in advance Interpretation: orforglipron 36mg achieved 1.7% A1C reduction at week 40; superior to 0.8% A1C reduction at week 40 achieved by dapagliflozin	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1849	Zolbetuximab (IMAB362) NCTID: NCT03816163 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CLDN18.2 inhibitor Area: Neoplasms Indication: 1L metastatic pancreatic adenocarcinoma (PDAC) Human Patients: 393 Sponsor: Astellas Pharma (ALPMY)	Date: 3 Dec 2024 Quarter: Q1'25 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS due to dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC alone)	Readout: 14 Oct 2025 Lead Time: 315 days in advance Interpretation: zolbetuximab + gemcitabine plus nab-paclitaxel failed to achieve superiority in OS compared with zolbetuximab + gemcitabine plus nab-paclitaxel alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1940	BOTOX NCTID: NCT05216250 Phase: Phase 2 Class: First-In-Class Modality: biologic toxin MoA: botulinum toxin type A Area: Nervous System Diseases Indication: Upper Limb Essential Tremor Human Patients: 174 Sponsor: AbbVie (ABBV)	Date: 24 Feb 2025 Quarter: Q2'25 Batch 12a Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in TREDs-R compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in TREDs-R/TETRAS UL inferior to propranolol)	Readout: 6 Oct 2025 Lead Time: 224 days in advance Interpretation: BOTOX achieved -1 placebo-adjusted improvement in TREDs-R total unilateral score (-2.61 vs -1.61 p=0.029); which is smaller than the 0.5-SD MCID threshold (>=4.2 point for TREDs-R)	Correct Prediction Conclusion: statistically significant weak clinical benefit and commercially probably insufficient (below-MCID improvement) Classification: True Negative (TN)
2053	Evolocumab NCTID: NCT03872401 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-PCSK9 inhibitor Area: Cardiovascular Diseases Indication: Patients with cardiovascular risk Human Patients: 12301 Sponsor: Amgen (AMGN)	Date: 31 Jul 2025 Quarter: Q4'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in MACE compared with placebo) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in MACE slightly superior to semaglutide yet moderately inferior to retatrutide)	Readout: 2 Oct 2025 Lead Time: 63 days in advance Interpretation: evolocumab + SoC met its primary endpoint in MACE reduction compared with SoC alone (detailed data undisclosed)	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
2055	MET097 NCTID: NCT06712836 Phase: Phase 2 Class: Best-In-Class Modality: peptide MoA: long-acting GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity without type	Date: 1 Aug 2025 Quarter: Q4'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in weight reduction compared with placebo) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in weight reduction)	Readout: 29 Sep 2025 Lead Time: 59 days in advance Interpretation: MET097i 1.2mg achieved 14.1% placebo-adjusted weight reduction at week 28 and 18.9%/3.8%/17.0% placebo-adjusted nausea/diarrhea/vomiting at week 12 in VESPER-3; slightly superior to 13% placebo-adjusted weight	Correct Prediction Conclusion: statistically significant and commercially sufficient (slightly superior to tirzepatide) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	2 diabetes Human Patients: 225 Sponsor: Metsera (MTSR)	slightly superior to tirzepatide yet slightly inferior to retatrutide)	reduction at week 28 and non-inferior to 21.5%/16.7%/10.5% placebo-adjusted nausea/diarrhea/vomiting at week 72 achieved by tirzepatide 15mg (see add'l link below)	
1992	Sonelokimab NCTID: NCT06411899 Phase: Phase 3 Class: Best-In-Class Modality: nanobody biologic MoA: trivalent nanobody that binds IL17A IL17F and serum albumin Area: Immune System Diseases Indication: Moderate to Severe Hidradenitis Suppurativa Human Patients: 422 Sponsor: MoonLake Immunotherapeutics (MLTX)	Date: 26 Apr 2025 Quarter: Q3'25 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in HiSCR75 compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in HiSCR75 slightly superior to bimekizumab and moderately superior to brivekimig)	Readout: 28 Sep 2025 Lead Time: 155 days in advance Interpretation: sonelokimab has achieved 18.3% placebo-adjusted HiSCR75; slightly superior to 18% placebo-adjusted HiSCR75 achieved by bimekizumab (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (slightly superior to bimekizumab) Classification: True Positive (TP)
2047	Carbetocin Nasal Spray NCTID: NCT06173531 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: intranasally delivered peptide as a synthetic analog of oxytocin Area: Nervous System Diseases Indication: Hyperphagia in Prader-Willi Syndrome (PWS) Human Patients: 170 Sponsor: ACADIA Pharmaceuticals (ACAD)	Date: 28 Jul 2025 Quarter: Q4'25 Batch 4 Technical: SUCCESS (statistically significant clinical benefit in HQCT compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in HQCT slightly-to-moderately superior to diazoxide choline)	Readout: 24 Sep 2025 Lead Time: 58 days in advance Interpretation: Carbetocin failed to meet the primary efficacy endpoint compared with placebo	Missed Prediction Note: due to suboptimal disease modeling of PWS that has been permanently improved Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1886	ZYN002 NCTID: NCT04977986 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: cannabidiol gel Area: Nervous System Diseases Indication: Fragile X Syndrome Human Patients: 215 Sponsor: Harmony Biosciences (HRMY)	Date: 26 Jan 2025 Quarter: Q2'25 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ABC-C FXS only for patients with complete FMR1 methylation) Commercial: SUCCESS (commercially sufficient yet weak clinical benefit in ABC-C FXS only for patients with complete FMR1 methylation due to no FDA approved drug on the market)	Readout: 24 Sep 2025 Lead Time: 241 days in advance Interpretation: ZYN002 failed to meet the primary efficacy endpoint compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1936	iberdomide NCTID: NCT04975997 Phase: Phase 3 Class: Best-In-Class Modality: molecular glue degrader MoA: cereblon E3 ligase modulator that degrades IKZF1 and IKZF3 Area: Neoplasms Indication: Relapsed or Refractory Multiple Myeloma Human Patients: 864 Sponsor: Bristol Myers Squibb (BMY)	Date: 4 Apr 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in ORR/PFS moderately superior to bortezomib + daratumumab + dexamethasone (DvD) and non-superior-non-inferior to belantamab mafodotin + pomalidomide + dexamethasone(BPd)) Commercial: SUCCESS (commercially sufficient additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in OS moderately superior bortezomib + daratumumab + dexamethasone (DvD) and slightly superior to belantamab mafodotin +	Readout: 23 Sep 2025 Lead Time: 172 days in advance Interpretation: iberdomide in combination with daratumumab and dexamethasone (IberDd) achieved a statistically significant superiority in MRD negativity (a deeper assessment than ORR) compared with the central arm of daratumumab/ bortezomib/dexamethasone (DvD); wait for OS data	Correct Prediction Conclusion: statistically significant (MRD negativity/ORR) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
		pomalidomide + dexamethasone(BPd)		
2029	MBX2109 (Canvuparatide) NCTID: NCT06465108 Phase: Phase 2 Class: First-In-Class Modality: peptide MoA: long-acting PTH prodrug Area: Endocrine System Diseases Indication: Hypoparathyroidism Human Patients: 64 Sponsor: MBX Biosciences (MBX)	Date: 1 Jun 2025 Quarter: Q3'25 Batch 12 Technical: FAILURE (statistically insignificant additive clinical benefit to SoC in the composite endpoint compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in the composite endpoint moderately inferior to eneboparatide)	Readout: 22 Sep 2025 Lead Time: 113 days in advance Interpretation: Canvuparatide achieved 63% response rate at week 12 (32% placebo-adjusted response rate $p=0.042$) in the composite primary endpoint (normal-ranged ADsCa maintenance and independence from conventional therapy); moderately inferior to eneboparatide that achieved 88% response rate at week 12 in the same composite primary endpoint (see add'l link below)	Correct Prediction Conclusion: statistically borderline significant and commercially probably insufficient (inferior to eneboparatide) Classification: True Negative (TN)
2013	Zilganersen (ION373) NCTID: NCT04849741 Phase: Phase 3 Class: First-In-Class Modality: antisense oligonucleotide (ASO) MoA: degrades GFAP mRNA Area: Nervous System Diseases Indication: Alexander Disease (AxD) Human Patients: 54 Sponsor: Ionis Pharmaceuticals (IONS)	Date: 7 May 2025 Quarter: Q3'25 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in 10MWT compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in 10MWT at most near the minimal clinically important difference MCID)	Readout: 22 Sep 2025 Lead Time: 138 days in advance Interpretation: Zilganersen achieved a statistically significant improvement in 10MWT at week 61 (mean difference 33.3% $p=0.0412$)	Correct Prediction Conclusion: statistically borderline significant and commercially maybe sufficient (depending on whether 10MWT improvement exceeds MCID) Classification: True Negative (TN)
1468	VS-01 NCTID: NCT05900050 Phase: Phase 2 Class: First-In-Class Modality: fluid MoA: liposomal-based intro-peritoneal fluid Area: Digestive System Diseases Indication: Acute-on-Chronic Liver Failure and Ascites Human Patients: 15 Sponsor: Genfit (GNFT)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 4 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 19 Sep 2025 Lead Time: 583 days in advance Interpretation: VS-01's further development has been discontinued for insufficient benefit/risk profile	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1950	Orforglipron NCTID: NCT06045221 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Inadequately Controlled With Metformin Human Patients: 1698 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in HbA1c and weight reduction compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction non-superior-non-inferior to semaglutide with numerically-inferior-to-semaglutide tolerability)	Readout: 17 Sep 2025 Lead Time: 171 days in advance Interpretation: orforglipron 36mg achieved 9.2% weight reduction; 2.2% A1C reduction; and 9.8% discontinuation rate at week 52; non-superior-non-inferior to 9.2% weight reduction; 2.0% A1C reduction; and est. 10% discontinuation rate at week 52 achieved by semaglutide oral 50mg (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (comparable efficacy and tolerability of orforglipron 36mg vs. oral semaglutide 50mg) Classification: True Positive (TP)
1856	Brivekimig (SAR442970) NCTID: NCT05849922 Phase: Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody that inhibits both TNFalpha and OX40L Area: Immune System Diseases Indication: Hidradenitis	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in HiSCR50 score against placebo) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in HiSCR50 score superior to adalimumab/povorcitinib)	Readout: 17 Sep 2025 Lead Time: 284 days in advance Interpretation: Brivekimig has achieved 30% placebo-adjusted HiSCR50 and 22% placebo-adjusted HiSCR90; superior to 24% placebo-adjusted HiSCR50 (10.1056/NEJMoa1504370) and 15% placebo-adjusted HiSCR90 achieved by adalimumab	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Suppurativa Human Patients: 86 Sponsor: Sanofi (SNY)	yet non-superior to sonelokimab/bimekizumab/secukinumab)	(10.1001/jamadermatol.2021.2905); yet non-superior to 24% placebo-adjusted HiSCR50 (10.1016/S0140-6736(24)00101-6) and 32% placebo-adjusted HiSCR90 achieved by bimekizumab (see add'l link below)	
1132	Brepocitinib NCTID: NCT05437263 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: JAK1/TYK2 inhibitor Area: Skin and Connective Tissue Diseases Indication: Dermatomyositis Human Patients: 241 Sponsor: Roivant Sciences (ROIV)	Date: 14 May 2025 Quarter: Q3'25 Batch 8 Technical: partial SUCCESS (statistically significant additive clinical benefit in TIS score compared with placebo for previously untreated patients) partial FAILURE (statistically insignificant clinical benefit in TIS score compared with placebo for previously treated patients) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit in TIS score compared with placebo for previously untreated patients) partial FAILURE (commercially insufficient clinical benefit in TIS score compared with placebo for previously treated patients)	Readout: 17 Sep 2025 Lead Time: 126 days in advance Interpretation: brepocitinib 30mg achieved 15.3 placebo-adjusted improvement in TIS at week 52 (p=0.0006)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1871	icotrokinra (JNJ-2113) NCTID: NCT06220604 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: oral anti-IL23R antagonist Area: Immune System Diseases Indication: Moderate to Severe Plaque Psoriasis Human Patients: 731 Sponsor: Johnson & Johnson / Protagonist Therapeutics (JNJ / PTGX)	Date: 14 Jan 2025 Quarter: Q2'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in IGA0/PASI90 superior to deucravacitinib) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in IGA0/PASI90 non-superior to bimekizumab)	Readout: 17 Sep 2025 Lead Time: 246 days in advance Interpretation: icotrokinra achieved 56% placebo-adjusted PASI90 at week 16 (p<0.0001); superior to deucravacitinib in the same trial; yet inferior to bimekizumab's 90% placebo-adjusted PASI90 at week 16 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (oral) Classification: True Positive (TP)
1870	icotrokinra (JNJ-2113) NCTID: NCT06143878 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: oral anti-IL23R antagonist Area: Immune System Diseases Indication: Moderate to Severe Plaque Psoriasis Human Patients: 774 Sponsor: Johnson & Johnson / Protagonist Therapeutics (JNJ / PTGX)	Date: 14 Jan 2025 Quarter: Q2'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in IGA0/PASI90 superior to deucravacitinib) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in IGA0/PASI90 non-superior to bimekizumab)	Readout: 17 Sep 2025 Lead Time: 246 days in advance Interpretation: icotrokinra achieved 51% placebo-adjusted PASI90 at week 16 (p<0.0001) superior to deucravacitinib in the same trial; yet inferior to bimekizumab's 90% placebo-adjusted PASI90 at week 16 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (oral) Classification: True Positive (TP)
2000	Intravenous Efgofitimid NCTID: NCT05415137 Phase: Phase 3 Class: First-In-Class Modality: fusion protein biologic MoA: NRP2 agonist Area: Respiratory Tract Diseases Indication: Pulmonary Sarcoidosis Human Patients: 268 Sponsor: aTyr Pharma (ATYR)	Date: 3 May 2025 Quarter: Q3'25 Batch 4 Technical: SUCCESS (statistically significant additive clinical benefit to OCS in FVC/KSQ-Lung compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit to OCS in FVC/KSQ-Lung slightly inferior to methotrexate +OCS)	Readout: 15 Sep 2025 Lead Time: 135 days in advance Interpretation: Efgofitimid failed to achieve the primary endpoint of replacing OCS compared with placebo at week 48 (-2.57mg vs -3.52 mg; p=0.3313); moderately inferior to methotrexate whose efficacy in FVC achieved non-inferiority compared with OCS and thus could replace OCS (see add'l link below); Efgofitimid + OCS achieved 4.17 improvement in KSQ-Lung score at week 48 (10.36 vs 6.19; p=0.0479)	Correct Prediction Conclusion: statistically partially significant and commercially maybe sufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1929	Rezatapopt (PC14586) NCTID: NCT04585750 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: p53 reactivator Area: Neoplasms Indication: advanced Solid Tumors Harboring a TP53 Y220C Mutation Human Patients: 300 Sponsor: PMV Pharmaceuticals (PMVP)	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit as monotherapy in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy in OS non-superior to SoC)	Readout: 10 Sep 2025 Lead Time: 208 days in advance Interpretation: Rezatapopt achieved 33% ORR; moderately superior to chemotherapy that achieved 10-20% ORR for advanced solid tumors (see add'l link below); wait for OS data	Correct Prediction Conclusion: statistically significant (superior ORR/PFS) and commercially TBD Classification: True Positive (TP)
2051	Zipalertinib (TAS6417) NCTID: NCT05967689 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: 3rd-gen pan-mutant wt-sparing EGFR TKI Area: Neoplasms Indication: ex20in-mt advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) Human Patients: 224 Sponsor: Taiho Oncology / Cullinan Therapeutics (CGEM)	Date: 31 Jul 2025 Quarter: Q4'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS compared with placebo at least numerically superior to osimertinib for cohort A/B/C/D) Commercial: SUCCESS (commercially sufficient clinical benefit in OS slightly-to-moderately superior to osimertinib for cohort A/B/C/D)	Readout: 9 Sep 2025 Lead Time: 40 days in advance Interpretation: Zipalertinib achieved a 62.5% ORR for 1L ex20in-mt NSCLC; moderately superior to osimertinib that achieved 25% ORR (see add'l link below); Zipalertinib achieved 21.9% ORR for 2L ex20in-mt NSCLCs; moderately superior to osimertinib that achieved 5% ORR (see DOI-10.1016/j.jtocrr.2022.100459); wait for OS data	Correct Prediction Conclusion: statistically significant (superior ORR/PFS) and commercially TBD Classification: True Positive (TP)
1729	Pumitamig (BNT327) NCTID: NCT06449209 Phase: Phase 2 Class: First-In-Class Modality: bispecific antibody (bsAb) MoA: anti-PDL1 and anti-VEGF Area: Neoplasms Indication: untreated extended-stage small-cell lung cancer (ES-SCLC) Human Patients: 110 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2025 Quarter: Q4'25 Batch 5 Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit in ORR/PFS numerically superior to ICI+chemotherapy as 1L treatment and numerically superior to chemotherapy as 2L/3L treatment) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to ICI+chemotherapy as 1L treatment and numerically superior to chemotherapy as 2L/3L treatment)	Readout: 8 Sep 2025 Lead Time: 30 days in advance Interpretation: Pumitamig + chemotherapy achieved 76.3% cORR and 6.8 months mPFS; numerically superior to the SoC atezolizumab + chemotherapy that achieved 60% cORR and 5.2 months mPFS (see add'l link below); wait for OS data	Correct Prediction Conclusion: statistically significant (numerically superior in ORR/PFS) and commercially TBD Classification: True Negative (TN)
1955	Pirtobrutinib (LOXO-305) NCTID: NCT05023980 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: non-covalent BTK inhibitor Area: Neoplasms Indication: Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL) Human Patients: 309 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q2'25 Batch 13b Technical: partial SUCCESS (statistically significant clinical benefit in ORR/PFS slightly superior to rituximab + bendamustine; slightly inferior to zanubrutinib/venetoclax + obinutuzumab) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to rituximab + bendamustine; slightly inferior to zanubrutinib/venetoclax + obinutuzumab)	Readout: 8 Sep 2025 Lead Time: 162 days in advance Interpretation: pirtobrutinib achieved superiority in PFS compared with bendamustine plus rituximab; wait for detailed PFS data for comparison with zanubrutinib/venetoclax + obinutuzumab; wait for OS data	Correct Prediction Conclusion: statistically significant (superior PFS compared with bendamustine plus rituximab) and commercially TBD Classification: True Positive (TP)
1908	Alixorexton (ALKS 2680) NCTID: NCT06358950 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: OX2R agonist Area: Nervous System Diseases Indication: Narcolepsy Type 1 Human Patients: 92	Date: 8 Feb 2025 Quarter: Q2'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in MWT for NT1 compared with placebo featuring a positive dose-response relationship) Commercial: SUCCESS	Readout: 7 Sep 2025 Lead Time: 211 days in advance Interpretation: Alixorexton met the primary endpoint in MSL on MWT at week 6 (24 min for 4mg with p=0.01; 26 minutes for 6mg with p<0.0001; 28 minutes for 8mg with p<0.0001) and the key secondary endpoint in ESS (-6.4 for 4mg with p=0.01; -8.7 for	Correct Prediction Conclusion: statistically significant and commercially sufficient (no approved treatment so far) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Alkermes (ALKS)	(commercially sufficient clinical benefit in MWT for NT1 non-inferior non-superior to ORX750/TAK861 in the best-case scenarios of optimal dosing regimens)	6mg with $p < 0.0001$; -8.3 for 8mg with $p < 0.0001$)	
1101	Inhaled Treprostinil NCTID: NCT05255991 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: synthetic analog of prostacyclin Area: Respiratory Tract Diseases Indication: Idiopathic Pulmonary Fibrosis Human Patients: 597 Sponsor: United Therapeutics (UTHR)	Date: 28 Jul 2025 Quarter: Q4'25 Batch 4 Technical: SUCCESS (statistically significant clinical benefit in FVC and OS compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in FVC and OS moderately superior to nerandomilast)	Readout: 2 Sep 2025 Lead Time: 36 days in advance Interpretation: Tyvaso as an add-on treatment achieved a 95.6mL placebo-adjusted improvement in absolute FVC at week 52 ($p < 0.0001$); moderately superior to nerandomilast that achieved a 68.8mL placebo-adjusted improvement in absolute FVC at week 52 ($p < 0.0001$) (see add'l link below)	Correct Prediction Conclusion: statistically significant (FVC) and commercially sufficient (moderately superior to nerandomilast in FVC) Classification: True Positive (TP)
1406	Olezarsen NCTID: NCT05552326 Phase: Phase 3 Class: Best-In-Class Modality: antisense oligonucleotide (ASO) MoA: GalNAc3-conjugated anti-APOC3 Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Severe Hypertriglyceridemia Human Patients: 446 Sponsor: Ionis Pharmaceuticals (IONS)	Date: 3 Jan 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit non-superior non-inferior to plozasiran)	Readout: 2 Sep 2025 Lead Time: 608 days in advance Interpretation: Olezarsen achieved 55-73% placebo-adjusted reduction in fasting triglycerides ($p < 0.0001$) and 85% placebo-adjusted reduction in acute pancreatitis attacks ($p < 0.0001$); non-superior-non-inferior to plozasiran that achieved 61-63% placebo-adjusted reduction in fasting triglycerides ($p < 0.001$) and 83% placebo-adjusted reduction in acute pancreatitis attacks ($p = 0.03$) (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-superior-non-inferior to plozasiran) Classification: True Positive (TP)
1965	Baxdrostat NCTID: NCT06034743 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective aldosterone synthase inhibitor Area: Cardiovascular Diseases Indication: Uncontrolled or resistant hypertension Human Patients: 796 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in seated SBP with a negative dose-response relationship) Commercial: FAILURE (commercially insufficient additive clinical benefit in seated SBP for the mixed uncontrolled/resistant hypertension patients without further resistance/biomarker-based stratifications; as baxdrostat; which is non-inferior non-superior to lorundrostat; could deliver commercially sufficient additive clinical benefit only for either resistant hypertension patients or uncontrolled hypertension patients featuring aberrant plasma aldosterone level/aldosterone-to-renin ratio)	Readout: 30 Aug 2025 Lead Time: 141 days in advance Interpretation: baxdrostat 2mg + SoC achieved 9.8 mmHg placebo-adjusted reduction in seated SBP at week 12 for uncontrolled or resistant hypertension ($p < 0.001$); and 10.3 mmHg seated SBP at week 12 for resistant hypertension ($p < 0.0001$ in Bax24 trial); which are non-superior to 6-12 mmHg placebo-adjusted 24hr ABPM reduction achieved by adding a third therapy to two standard anti-hypertension medications (see add'l link below and DOI-10.1016/j.ejim.2023.04.021)	Correct Prediction Conclusion: statistically significant (weak additive efficacy) and commercially maybe sufficient (more benefit for resistant hypertension than for uncontrolled hypertension) Classification: True Positive (TP)
2008	Zilebesiran NCTID: NCT06272487 Phase: Phase 2 Class: First-In-Class Modality: siRNA MoA: GalNAc-conjugated siRNA against liver-expressed AGT Area: Cardiovascular Diseases Indication: Uncontrolled hypertension Human Patients: 375	Date: 06 May 2025 Quarter: Q3'25 Batch 5 Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in seated SBP compared with placebo) Commercial: partial FAILURE (commercially maybe sufficient yet very weak additive clinical benefit to SoC in seated SBP moderately	Readout: 30 Aug 2025 Lead Time: 116 days in advance Interpretation: zilebesiran didn't achieve statistical significance with 5.0 mmHg placebo-adjusted reduction in seated SBP at week 12 for uncontrolled hypertension ($p = 0.0431$); moderately inferior to baxdrostat that achieved 9.8 mmHg placebo-adjusted reduction in seated SBP at week 12 for uncontrolled or resistant hypertension ($p < 0.001$) (see	Correct Prediction Conclusion: statistically insignificant and commercially insufficient (inferior to baxdrostat) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Alynlyam Pharmaceuticals / Roche (ALNY/RHHBY)	inferior to low-dose baxdrostat/lorundrostat + SoC)	add'l link below and DOI-10.1016/j.ejim.2023.04.021)	
1375	AMX0035 NCTID: NCT06122662 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: sodium phenylbutyrate + taurursodiol Area: Nervous System Diseases Indication: Progressive Supranuclear Palsy Human Patients: 110 Sponsor: Amylyx Pharmaceuticals (AMLX)	Date: 26 Apr 2025 Quarter: Q2'25 Batch 14e Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in PSPRS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in PSPRS though no FDA approved drug is available)	Readout: 27 Aug 2025 Lead Time: 123 days in advance Interpretation: AMX0035 failed to meet any primary or secondary endpoint; further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
2015	VK2735 NCTID: NCT06828055 Phase: Phase 2 Class: Best-In-Class Modality: peptide MoA: oral GLP1R/GIPR dual agonist Area: Nutritional and Metabolic Diseases Indication: obesity without type 2 diabetes Human Patients: 280 Sponsor: Viking Therapeutics (VKTX)	Date: 8 May 2025 Quarter: Q3'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in weight reduction compared with placebo with superior-to-tirzepatide tolerability) Commercial: SUCCESS (commercially sufficient clinical benefit in weight reduction non-superior-non-inferior to retatrutide; moderately superior to tirzepatide; and strongly superior to orforglipron/GSBR1290/cagrisema)	Readout: 26 Aug 2025 Lead Time: 110 days in advance Interpretation: VK2735 oral 90mg achieved 9.8% placebo-adjusted weight reduction and 7% placebo-adjusted discontinuation rate at week 13; superior to 5.5% placebo-adjusted weight reduction at week 13 and superior to 7.7% placebo-adjusted discontinuation rate at week 72 achieved by orforglipron 36mg (see add'l link below); superior to 6.2% placebo-adjusted weight reduction at week 13 yet inferior to 3.6% placebo-adjusted discontinuation rate at week 72 achieved by tirzepatide 15mg (10.1056/NEJMoa2206038)	Correct Prediction Conclusion: statistically significant and commercially sufficient (strongly superior efficacy compared with both orforglipron and tirzepatide and non-inferior tolerability compared with orforglipron) Classification: True Positive (TP)
1954	Orforglipron NCTID: NCT05872620 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity or Overweight and Type 2 Diabetes Human Patients: 1613 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in weight reduction and HbA1c compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction non-superior-non-inferior to semaglutide/GSBR1290 with numerically-inferior-to-semaglutide tolerability)	Readout: 26 Aug 2025 Lead Time: 149 days in advance Interpretation: orforglipron 36mg achieved 8.3% placebo-adjusted weight reduction and 6% placebo-adjusted discontinuation rate at week 72; overall non-superior-non-inferior to 6.2% placebo-adjusted weight reduction and 3.3% placebo-adjusted discontinuation rate at week 68 achieved by semaglutide 2.4mg (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient (slightly superior efficacy yet slightly inferior tolerability compared with semaglutide; thus commercially more competitive for obesity with T2DM than for obesity without T2DM) Classification: True Positive (TP)
1207	Barzolvlimab (CDX-0159) NCTID: NCT05774184 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-cKIT inhibitor Area: Immune System Diseases Indication: Eosinophilic Esophagitis (EoE) Human Patients: 86 Sponsor: Celldex Therapeutics (CLDX)	Date: 15 May 2025 Quarter: Q3'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in DSQ compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in DSQ slightly superior to dupilumab)	Readout: 19 Aug 2025 Lead Time: 96 days in advance Interpretation: barzolvlimab failed to achieve the primary efficacy endpoint in DSQ (p=0.33)	Missed Prediction Note: due to suboptimal disease model that has been permanently improved Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1721	SGR-2921 NCTID: NCT05961839 Phase: Phase 1 Class: First-In-Class	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant (additive) clinical benefit	Readout: 14 Aug 2025 Lead Time: 373 days in advance Interpretation: SGR-2921's further development has been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule MoA: CDC7 inhibitor Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia or Myelodysplastic Syndrome Human Patients: 66 Sponsor: Schrödinger (SDGR)	in ORR/PFS) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS)	due to unfavourable clinical benefit/risk profile	Classification: True Negative (TN)
1500	Troriluzole NCTID: NCT04641143 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: riluzole prodrug Area: Mental Disorders Indication: Obsessive Compulsive Disorder Human Patients: 700 Sponsor: Biohaven Pharmaceuticals (BHAVN)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 11 Aug 2025 Lead Time: 523 days in advance Interpretation: troriluzole failed to achieve the efficacy primary endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1499	Troriluzole NCTID: NCT04693351 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: riluzole prodrug Area: Mental Disorders Indication: Obsessive Compulsive Disorder Human Patients: 589 Sponsor: Biohaven Pharmaceuticals (BHAVN)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 11 Aug 2025 Lead Time: 523 days in advance Interpretation: troriluzole failed to achieve the efficacy primary endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1953	Orforglipron NCTID: NCT05869903 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity or Overweight With Weight-Related Comorbidities Human Patients: 3127 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in weight reduction and HbA1c compared with placebo) Commercial: partial SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction non-superior-non-inferior to semaglutide/GSBR1290 with slightly-inferior-to-semaglutide tolerability)	Readout: 7 Aug 2025 Lead Time: 130 days in advance Interpretation: orforglipron 36mg achieved 11.5% placebo-adjusted weight reduction and 7.7% placebo-adjusted discontinuation rate at week 72; slightly inferior to 15.1% placebo-adjusted weight reduction 3.7 % placebo-adjusted discontinuation rate at week 72 achieved by semaglutide 2.4mg (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (slightly inferior efficacy yet moderately inferior tolerability compared with semaglutide) Classification: True Negative (TN)
1805	CardiolRx NCTID: NCT05180240 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral cannabidiol Area: Cardiovascular Diseases Indication: Acute Myocarditis Human Patients: 109 Sponsor: Cardiol Therapeutics (CRDL)	Date: 19 Oct 2024 Quarter: Q1'25 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in LVEF/KCCQ/mortality against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in LVEF/KCCQ/mortality non-superior to beta blockers yet there is no FDA approved treatments specifically for acute myocarditis)	Readout: 6 Aug 2025 Lead Time: 291 days in advance Interpretation: CardiolRx has met the ECV primary endpoint (p=0.0538) and has not met its GLS primary endpoint	Correct Prediction Conclusion: statistically maybe significant and commercially maybe sufficient Classification: True Negative (TN)
625	AT-1501 (Tegoprubart) NCTID: NCT05027906 Phase: Phase 1 Phase 2	Date: 26 Jan 2025 Quarter: Q2'25 Batch 6 Technical: partial SUCCESS	Readout: 6 Aug 2025 Lead Time: 192 days in advance Interpretation: tegoprubart stabilized	Correct Prediction Conclusion: statistically maybe significant (iBox) and commercially

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CD40L inhibitor Area: Immune System Diseases Indication: prevention of rejection in kidney transplantation Human Patients: 48 Sponsor: Eledon Pharmaceuticals (ELDN)	(statistically maybe significant yet weak additive clinical benefit in eGFR compared with placebo featuring negative dose-response relationship) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in eGFR/graft survival/BPAR at most numerically superior to tacrolimus)	eGFR at 63 mL/min/1.73 m2 and achieved -4.11 iBox score at 12 months; both are numerically superior to calcineurin inhibitors (e.g. tacrolimus) that stabilised eGFR at 53 mL/min/1.73 m2 and achieved -2.98 iBox score at 12 months	maybe sufficient (weak efficacy in eGFR) Classification: True Negative (TN)
727	Tirzepatide NCTID: NCT04255433 Phase: Phase 3 Class: Best-In-Class Modality: peptide MoA: GLP1R/GIPR dual agonist Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Mellitus (T2DM) and heart disease Human Patients: 13299 Sponsor: Eli Lilly and Company (LLY)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit superior to dulaglutide in MACE-3 endpoint for obese diabetic cardiovascular patients)	Readout: 31 Jul 2025 Lead Time: 529 days in advance Interpretation: Tirzepatide achieved 8% dulaglutide-adjusted reduction in MACE-3 (HR = 0.92 p=0.086); 16% dulaglutide-adjusted reduction in time to all-cause death (HR=0.84; p=0.002); and 28% placebo-adjusted reduction in MACE-3 (HR = 0.72); superior to semaglutide's 20% placebo-adjusted reduction in MACE-3 in SELECT trial (see add'l link below)	Correct Prediction Conclusion: statistically insignificant (numerically superior to dulaglutide) and commercially sufficient (numerically superior to semaglutide) Classification: True Positive (TP)
1944	VYN201 (repibresib) NCTID: NCT06493578 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: BET inhibitor Area: Skin and Connective Tissue Diseases Indication: Non-segmental Vitiligo Human Patients: 200 Sponsor: Vyne Therapeutics (VYNE)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 12b Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in F-VASI50/T-VASI50 compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in F-VASI50/T-VASI50 inferior to baricitinib/ruxolitinib/upadacitinib)	Readout: 30 Jul 2025 Lead Time: 125 days in advance Interpretation: repibresib failed to achieve the primary endpoint in F-VASI50 at week 24	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1937	Upadacitinib NCTID: NCT06012240 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: pan-JAK inhibitor with higher efficacy against JAK1 Area: Skin and Connective Tissue Diseases Indication: Alopecia Areata Human Patients: 1500 Sponsor: AbbVie (ABBV)	Date: 24 Feb 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in SALT<=20 compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in SALT<=20/SALT<=10 moderately superior to baricitinib)	Readout: 30 Jul 2025 Lead Time: 156 days in advance Interpretation: Upadacitinib achieved 50.9% placebo-adjusted SALT20 response at week 24; moderately superior to ritlecitinib that achieved 29.1% placebo-adjusted SALT20 response at week 24 (see add'l link below) and moderately superior to baricitinib that achieved 28% placebo-adjusted SALT20 response at week 24 (see DOI-10.1056/NEJMoa2110343)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1956	Pirtobrutinib (LOXO-305) NCTID: NCT05254743 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: non-covalent BTK inhibitor Area: Neoplasms Indication: Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Human Patients: 662 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q2'25 Batch 13b Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS at most slightly superior to ibrutinib) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to ibrutinib)	Readout: 29 Jul 2025 Lead Time: 121 days in advance Interpretation: pirtobrutinib achieved non-inferiority in ORR compared with ibrutinib; wait for PFS/OS data	Correct Prediction Conclusion: statistically insignificant (non-superior) and commercially TBD Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1844	ATI-2138 NCTID: NCT06585202 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral anti-ITK and anti-JAK3 dual inhibitor Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Atopic Dermatitis Human Patients: 14 Sponsor: Aclaris Therapeutics (ACRS)	Date: 10 Nov 2024 Quarter: Q1'25 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in EASI75 superior to dupilumab and superior to upadacitinib)	Readout: 29 Jul 2025 Lead Time: 261 days in advance Interpretation: ATI2138 achieved 77.1% mean EASI score improvement at week 12 ($p < 0.001$); superior to dupilumab's 67.5% mean EASI score improvement at week 12 (see add'l link below); and superior to upadacitinib's 69.2% mean EASI score improvement at week 12-16 (see DOI-10.1016/j.ad.2024.10.067)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)
1561	Onvansertib NCTID: NCT06106308 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: PLK1 inhibitor Area: Neoplasms Indication: KRAS/NRAS-mutant 1L mCRC Human Patients: 113 Sponsor: Cardiff Oncology (CRDF)	Date: 24 Apr 2024 Quarter: Q3'24 Batch 2 Technical: FAILURE (statistically insignificant additive clinical benefit in ORR with additive toxicity) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS with additive toxicity)	Readout: 29 Jul 2025 Lead Time: 461 days in advance Interpretation: onvansertib 30mg + chemotherapy + bevacizumab achieved 49% cORR that's numerically superior to 30% cORR achieved by chemotherapy + bevacizumab (no p-value provided); onvansertib 30mg + chemotherapy + bevacizumab achieved statistically insignificant mPFS improvement compared with chemotherapy + bevacizumab (no p-value provided)	Correct Prediction Conclusion: statistically probably insignificant and commercially TBD (wait for OS data) Classification: True Negative (TN)
1990	— NCTID: NCT05686239 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Inidascamine (RL-007) Area: Nervous System Diseases Indication: Cognitive Impairment Associated With Schizophrenia Human Patients: 242 Sponsor: ATAI Life Sciences (ATAI)	Date: 24.Apr.25 Quarter: Q3'25 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in MCCB compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit in MCCB inferior to KarXT)	Readout: 25 Jul 2025 Lead Time: — Interpretation: inidascamine failed to achieve the primary endpoint in MCCB score at week 6	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
2020	KB304 NCTID: NCT06724900 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: HSV1 gene therapy delivering COL3A1 and ELN transgenes Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Wrinkles of the Décolleté Human Patients: 376 Sponsor: Krystal Biotech (KRYS)	Date: 13.May.25 Quarter: Q3'25 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit in wrinkle reduction compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in wrinkle reduction slightly inferior to KB301)	Readout: 24 Jul 2025 Lead Time: — Interpretation: KB304 achieved numerically higher subject-reported ≥ 1 point GAIS improvement at three months (72.7% vs 14.3%; no p-value reported); no data reported for improvements in wrinkle severity such as JDWS	Correct Prediction Conclusion: statistically maybe insignificant (no p-value reported) and commercially TBD Classification: True Negative (TN)
1751	belantamab mafodotin NCTID: NCT04484623 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-BCMA ADC Area: Neoplasms Indication: Relapsed / Multiple Myeloma Human Patients: 302 Sponsor: GlaxoSmithKline (GSK)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS superior to bortezomib when combined with pomalidomide + dexamethasone) partial FAILURE (statistically insignificant additive clinical benefit in ORR non-superior to bortezomib) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to bortezomib when	Readout: 17 Jul 2025 Lead Time: 336 days in advance Interpretation: belantamab mafodotin + bortezomib + dexamethasone (BVD) achieved 48% reduction in the risk of progression (PFS HR = 0.52 $p = 0.0001$) and statistically insignificant reduction in the risk of death (OS HR = 0.77 $p = 0.1896$) compared with daratumumab + bortezomib + dexamethasone (DvD)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (FDA disapproval recommendation due to overall insufficient OS benefit given insignificant OS in DREAMM 8 despite significant OS in DREAMM 7) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
		combined with pomalidomide + dexamethasone)		
1750	belantamab mafodotin NCTID: NCT04246047 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-BCMA ADC Area: Neoplasms Indication: Relapsed / Multiple Myeloma Human Patients: 494 Sponsor: GlaxoSmithKline (GSK)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS superior to daratumumab when combined with bortezomib + dexamethasone) partial FAILURE (statistically insignificant additive clinical benefit in ORR non-superior to daratumumab) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to daratumumab when combined with bortezomib + dexamethasone)	Readout: 17 Jul 2025 Lead Time: 336 days in advance Interpretation: belantamab mafodotin + bortezomib + dexamethasone (BvD) achieved 59% reduction in the risk of progression (PFS HR = 0.41 p<0.001) and 42% reduction in the risk of death (OS HR=0.58 p=0.00023) compared with daratumumab + bortezomib + dexamethasone (DVd)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (FDA disapproval recommendation due to overall insufficient OS benefit given insignificant OS in DREAMM 8 despite significant OS in DREAMM 7) Classification: True Negative (TN)
1968	CAEL-101 (anselamimab) NCTID: NCT04504825 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: IgG1 monoclonal antibody that binds to a conformational neopeptide contained with the first 18 amino acids of misfolded human immunoglobulin light chains Area: Cardiovascular Diseases Indication: AL amyloidosis Human Patients: 125 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit to CyBorD in all-cause mortality/frequency of hospitalization/KCCQ/6MWT compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit to CyBorD in all-cause mortality/frequency of hospitalization/KCCQ/6MWT inferior to daratumumab + CyBorD)	Readout: 16 Jul 2025 Lead Time: 96 days in advance Interpretation: Anselamimab failed to achieve the primary endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1967	CAEL-101 (anselamimab) NCTID: NCT04512235 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: IgG1 monoclonal antibody that binds to a conformational neopeptide contained with the first 18 amino acids of misfolded human immunoglobulin light chains Area: Cardiovascular Diseases Indication: AL amyloidosis Human Patients: 281 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit to CyBorD in all-cause mortality/frequency of hospitalization/KCCQ/6MWT compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit to CyBorD in all-cause mortality/frequency of hospitalization/KCCQ/6MWT inferior to daratumumab + CyBorD)	Readout: 16 Jul 2025 Lead Time: 96 days in advance Interpretation: Anselamimab failed to achieve the primary endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1911	TAK861 NCTID: NCT06470828 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: OX2R agonist Area: Nervous System Diseases Indication: Narcolepsy Type 1 Human Patients: 168 Sponsor: Takeda (TAK)	Date: 8 Feb 2025 Quarter: Q2'25 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in MWT for NT1 compared with placebo featuring a positive dose-response relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in MWT for NT1 non-inferior non-superior to ORX750/ALKS2680 in the best-case scenarios of optimal dosing regimens)	Readout: 14 Jul 2025 Lead Time: 156 days in advance Interpretation: TAK861 met all primary and secondary endpoints	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1910	TAK861 NCTID: NCT06505031	Date: 8 Feb 2025 Quarter: Q2'25 Batch 11	Readout: 14 Jul 2025 Lead Time: 156 days in advance	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: OX2R agonist Area: Nervous System Diseases Indication: Narcolepsy Type 1 Human Patients: 105 Sponsor: Takeda (TAK)	Technical: SUCCESS (statistically significant clinical benefit in MWT for NT1 compared with placebo featuring a positive dose-response relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in MWT for NT1 non-inferior non-superior to ORX750/ALKS2680 in the best-case scenarios of optimal dosing regimens)	Interpretation: TAK861 met all primary and secondary endpoints	and commercially sufficient Classification: True Positive (TP)
1995	briquilimab NCTID: NCT06592768 Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody MoA: aglycosylated anti-ckIT inhibitor Area: Respiratory Tract Diseases Indication: Allergic Asthma Human Patients: 17 Sponsor: Jasper Therapeutics (JSPR)	Date: 26 Apr 2025 Quarter: Q3'25 Batch 3 Technical: partial FAILURE (statistically maybe significant yet very weak clinical benefit in allergy-induced LAR/EAR compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit allergy-induced LAR/EAR non-superior to SoC)	Readout: 7 Jul 2025 Lead Time: 72 days in advance Interpretation: briquilimab's further development has been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
780	Bezuclastinib NCTID: NCT05186753 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: ckIT D816V-mutation inhibitor Area: Neoplasms Indication: Indolent or Smoldering Systemic Mastocytosis Human Patients: 237 Sponsor: Cogent Biosciences (COGT)	Date: 14 Jan 2025 Quarter: Q3'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in MS2D2 non-superior-to avapritinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit featuring superior-to-avapritinib efficacy in OS and superior-to-avapritinib toxicity)	Readout: 7 Jul 2025 Lead Time: 174 days in advance Interpretation: bezuclastinib achieved placebo-adjusted -8.9 point in TSS/MS2D2 at week 24 (-24.3 bezuclastinib vs -15.4 placebo; 58% improvement over placebo; p=0.0002); numerically superior to avapritinib's placebo-adjusted -6.4 point in TSS/MS2D2 at week 24 (-15.6 avapritinib vs -9.2 placebo; 70% improvement over placebo; p < 0.003) (see add'l link below)	Correct Prediction Conclusion: statistically significant (TSS/MS2D2) and commercially TBD (wait for OS data) Classification: True Positive (TP)
1882	APG777 NCTID: NCT06395948 Phase: Phase 2 Class: Best-In-Class Modality: monoclonal antibody MoA: YTE-and-LALA-modified anti-IL13 inhibitor Area: Skin and Connective Tissue Diseases Indication: moderate-to-severe Atopic Dermatitis Human Patients: 431 Sponsor: Apogee Therapeutics (APGE)	Date: 23 Jan 2025 Quarter: Q2'25 Batch 5 Technical: SUCCESS (statistically significant clinical benefit in EASI75 compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in EASI75 at least numerically superior to lebrikizumab yet still inferior to upadacitinib)	Readout: 7 Jul 2025 Lead Time: 165 days in advance Interpretation: APG777 achieved 42.3% placebo-adjusted EASI75 at week 16 (p < 0.001); numerically superior to lebrikizumab's 38% placebo-adjusted EASI75 at week 16 averaged from two phase 3 trials (see 10.1056/NEJMoa2206714); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1692	BPL-003 NCTID: NCT05870540 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: intranasal 5-MeO-DMT Area: Mental Disorders Indication: Treatment Resistant Depression Human Patients: 196 Sponsor: atai Life Sciences (ATAI)	Date: 24 Apr 2025 Quarter: Q3'25 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in MADRS compared with placebo) Commercial: partial SUCCESS (commercially sufficient clinical benefit non-superior-non-inferior to GH001; moderately superior to esketamine + SNRI/SSRI; yet moderately inferior to CYB003)	Readout: 1 Jul 2025 Lead Time: 68 days in advance Interpretation: BPL003 (8mg) achieved statistically significant -12.1 points MADRS reduction at Day 29 (p = 0.0025); superior to esketamine that achieved placebo-adjusted -9 points MADRS reduction at Day 8 (see add'l link below); yet non-superior to -15.5 points MADRS reduction at Day 8 by GH001 (p<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient (superior to esketamine) Classification: True Positive (TP)
1300	XPro1595	Date: 21 Aug 2024	Readout: 30 Jun 2025	Correct Prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05318976 Phase: Phase 2 Class: First-In-Class Modality: recombinant protein biologic MoA: biologic soluble TNFalpha neutralizer Area: Nervous System Diseases Indication: Early Alzheimer's Disease With Biomarkers of Inflammation Human Patients: 208 Sponsor: Immune Bio (INMB)	Quarter: Q1'25 Batch 11 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in EMACC for neuroinflammation-biomarker-stratified mild AD patients) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in CDR/ADCS-ADL at most numerically superior to lecanemab for neuroinflammation-biomarker-stratified mild AD patients)	Lead Time: 313 days in advance Interpretation: XPro1595 did not meet the primary cognitive endpoint EMACC in the mITT population; yet a clinical benefit in EMACC (effect size 0.27) is observed for early Alzheimer's patients with two or more biomarkers of inflammation at baseline	Conclusion: statistically insignificant and commercially probably insufficient Classification: True Negative (TN)
492	ARCT810 NCTID: NCT05526066 Phase: Phase 2 Class: First-In-Class Modality: mRNA medicine MoA: LNP-delivered OTC Area: Nervous System Diseases Indication: Ornithine Transcarbamylase Deficiency (OTCD) Human Patients: 8 Sponsor: Arcturus Therapeutics (ARCT)	Date: 14 Feb 2024 Quarter: Q4'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 30 Jun 2025 Lead Time: 502 days in advance Interpretation: ARCT810 achieved -2.5 µmol/L/day glutamine levels and +14.7% RUF (p=0.026)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient (no FDA approved drug for OTCD) Classification: True Positive (TP)
1339	Pemvidutide NCTID: NCT05989711 Phase: Phase 2 Class: First-In-Class Modality: peptide MoA: GLP1R/GCGR dual agonist Area: Nutritional and Metabolic Diseases Indication: Non-Alcoholic Steatohepatitis (NASH) Human Patients: 190 Sponsor: Altimune (ALT)	Date: 14 Jan 2025 Quarter: Q2'25 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in both NASH resolution and fibrosis improvement compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in both NASH resolution and fibrosis improvement inferior to tirzepatide)	Readout: 26 Jun 2025 Lead Time: 163 days in advance Interpretation: pemvidutide achieved 8.6% placebo-adjusted fibrosis improvement with no worsening of steatohepatitis (statistically insignificant) and 33% placebo-adjusted steatohepatitis resolution with no worsening of fibrosis (p<0.0001 at week 24; inferior to tirzepatide's 21% and 52% delta at week 52 (see add'l link below); and inferior to efruxifermin's 21% and 61% delta at week 24 (see DOI-10.1001/jamanetworkopen.2022.31982)	Correct Prediction Conclusion: partially statistically significant and commercially insufficient Classification: True Negative (TN)
1824	SAR444656 (KT-474) NCTID: NCT06028230 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: E3ligase-binding IRAK4 degrader Area: Immune System Diseases Indication: Moderate to Severe Hidradenitis Suppurativa Human Patients: 70 Sponsor: Kymera Therapeutics / Sanofi (KYMR / SNY)	Date: 4 Nov 2024 Quarter: Q1'25 Batch 6 Technical: SUCCESS (statistically significant yet moderate clinical benefit in HiSCR50 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in HiSCR50 non-superior to adalimumab and inferior to sonelokimab/bimekizumab/secukinumab)	Readout: 25 Jun 2025 Lead Time: 233 days in advance Interpretation: SAR444656's further development is discontinued	Correct Prediction Conclusion: statistically TBD and commercially insufficient Classification: True Negative (TN)
1822	SAR444656 (KT-474) NCTID: NCT06058156 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: E3ligase-binding IRAK4 degrader Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Atopic Dermatitis Human Patients: 70	Date: 4 Nov 2024 Quarter: Q1'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-superior to upadacitinib)	Readout: 25 Jun 2025 Lead Time: 233 days in advance Interpretation: SAR444656's further development is discontinued	Correct Prediction Conclusion: statistically TBD and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Kymera Therapeutics / Sanofi (KYMR / SNY)			
1248	Zidesamtinib (NVL-520) NCTID: NCT05118789 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: CNS-penetrant mutant-selective ROS1 inhibitor Area: Neoplasms Indication: Advanced NSCLC and Other Solid Tumors Human Patients: 359 Sponsor: Nuvalent (NUVL)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo non-inferior to repotrectinib for tumors with ROS1 fusion without TRK fusion) Commercial: SUCCESS (commercially sufficient clinical benefit in OS superior to repotrectinib for tumors with ROS1 fusion without TRK fusion)	Readout: 24 Jun 2025 Lead Time: 313 days in advance Interpretation: Zidesamtinib achieved 44% ORR; superior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR for EGFRwt advanced NSCLC patients (see DOI-10.1016/j.lungcan.2018.12.015) and slightly superior to repotrectinib that achieved 38% ORR for ROS1-positive advanced NSCLC (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1820	Repegaldesleukin (Rezpeg) NCTID: NCT06136741 Phase: Phase 2 Class: First-In-Class Modality: PEGylated peptide MoA: pegylated recombinant protein IL2 agonist Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Atopic Dermatitis Human Patients: 396 Sponsor: Nektar Therapeutics (NKTR)	Date: 3 Nov 2024 Quarter: Q1'25 Batch 6 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab or upadacitinib)	Readout: 24 Jun 2025 Lead Time: 233 days in advance Interpretation: repegaldesleukin achieved 25% placebo-adjusted EASI75 at week 16; inferior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see DOI-10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to both dupilumab and upadacitinib) Classification: True Negative (TN)
1875	ST920 NCTID: NCT04046224 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV2/6-delivered GLA gene therapy Area: Nervous System Diseases Indication: Fabry Disease Human Patients: 33 Sponsor: Sangamo Therapeutics (SGMO)	Date: 19 Jan 2025 Quarter: Q2'25 Batch 3 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in eGFR compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in eGFR inferior to pegunigalsidase alfa)	Readout: 24 Jun 2025 Lead Time: 156 days in advance Interpretation: ST920 achieved a positive yet statistically insignificant eGFR slope at week 52	Correct Prediction Conclusion: statistically maybe insignificant and commercially TBD Classification: True Negative (TN)
1438	COMP360 NCTID: NCT05642428 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: 5HT2AR agonist Area: Mental Disorders Indication: treatment-resistant depression (TRD) Human Patients: 255 Sponsor: Compass Pathways (CMPS)	Date: 11 Feb 2025 Quarter: Q2'25 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to SoC and to 5-MeO-DMT)	Readout: 23 Jun 2025 Lead Time: 132 days in advance Interpretation: COMP360 achieved statistically significant -3.6 points MADRS reduction at Week 6 (p <0.001); inferior to esketamine that achieved placebo-adjusted -9 points MADRS reduction at Day 8 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1720	Apitegromab NCTID: NCT06445075 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: latent myostatin inhibitor Area: Nutritional and Metabolic Diseases Indication: GLP1RA-related Muscle Preservation for Overweight and Obesity Human Patients: 100	Date: 6 Aug 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant additive clinical benefit in weight reduction; total lean body mass preservation; and total fat body mass reduction) Commercial: SUCCESS (commercially sufficient additive clinical benefit in weight reduction; total lean body mass preservation;	Readout: 18 Jun 2025 Lead Time: 316 days in advance Interpretation: apitegromab achieved a placebo-adjusted 15.6% reduction of muscle loss percentage (p=0.001) at week 24 superior to tirzepatide; and a placebo-adjusted 15.8% increase of fat loss percentage at week 24 superior to tirzepatide; and a placebo-adjusted 1.1% weight gain at week 24 compared with tirzepatide	Correct Prediction Conclusion: statistically significant and commercially sufficient (85% fat mass/15% lean mass compared to tirzepatide alone (70% fat mass/30% lean mass) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Scholar Rock (SRRK)	and total fat body mass reduction; superior to semaglutide/tirzepatide monotherapy)		
1905	VTX3232 NCTID: NCT06556173 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant NLRP3 inhibitor Area: Nervous System Diseases Indication: early Parkinson's Disease (PD) Human Patients: 11 Sponsor: Ventyx Biosciences (VTYX)	Date: 8 Feb 2025 Quarter: Q2'25 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in MDS-UPDRS compared with placebo featuring moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in MDS-UPDRS compared with levodopa/tapapadon monotherapy)	Readout: 17 Jun 2025 Lead Time: 129 days in advance Interpretation: VTX3232's improvement in MDS-UPDRS Parts II and III combined score at week 6 was neither disclosed nor statistically significant; non-superior to -10.2 improvement in MDS-UPDRS total score achieved by Levodopa at week 26 (see add'l link below)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1393	Lorundrosta NCTID: NCT06150924 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: aldosterone synthase inhibitor Area: Cardiovascular Diseases Indication: hypertension and Chronic Kidney Disease (CKD) with albuminuria Human Patients: 60 Sponsor: Mineralys Therapeutics (MLYS)	Date: 26 Jul 2024 Quarter: Q1'25 Batch 4 Technical: SUCCESS (statistically significant additive clinical benefit in AOBP SBP) Commercial: SUCCESS (commercially sufficient additive clinical benefit in AOBP SBP for lorundrostat + dapagliflozin combotherapy adjunctive treatment which would be non-superior to lorundrostat monotherapy adjunctive treatment)	Readout: 17 Jun 2025 Lead Time: 326 days in advance Interpretation: lorundrostat + dapagliflozin achieved a 7.5 mmHg placebo-adjusted reduction in systolic blood pressure at week 4 (p=0.0024)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)
1881	SPY072 NCTID: NCT06622070 Phase: Phase 1 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-TL1A inhibitor Area: Immune System Diseases Indication: rheumatoid arthritis (RA); psoriatic arthritis (PsA); axial spondyloarthritis (axSpA) Human Patients: 56 Sponsor: Spyre Therapeutics (SYRE)	Date: 22 Jan 2025 Quarter: Q2'25 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit in clinical remission and endoscopic response compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in clinical remission and endoscopic response inferior to MK7240/TEV574)	Readout: 17 Jun 2025 Lead Time: 146 days in advance Interpretation: SPY072 achieved a comparable PK to SPY002 without >= Grade 2 TEAEs	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1880	SPY002 NCTID: NCT06672718 Phase: Phase 1 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-TL1A inhibitor Area: Immune System Diseases Indication: Ulcerative Colitis Human Patients: 56 Sponsor: Spyre Therapeutics (SYRE)	Date: 22 Jan 2025 Quarter: Q2'25 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit in clinical remission and endoscopic response compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in clinical remission and endoscopic response inferior to MK7240/TEV574)	Readout: 17 Jun 2025 Lead Time: 146 days in advance Interpretation: SPY002 achieved a 75-day half-life which is more than 3-fold greater than 1st-gen anti-TL1As; without >= Grade 2 TEAEs	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1623	Venetoclax NCTID: NCT04401748 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: BCL2 inhibitor Area: Neoplasms Indication: 1L higher-risk myelodysplastic syndrome (HR-MDS)	Date: 24 Feb 2025 Quarter: Q2'25 Batch 12a Technical: SUCCESS (statistically significant additive clinical benefit in CR) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS)	Readout: 16 Jun 2025 Lead Time: 112 days in advance Interpretation: venetoclax + azacitidine failed to meet the primary endpoint of OS (HR = 0.908 p = 0.3772) compared with azacitidine alone	Missed Prediction Note: due to suboptimal modelling of venetoclax's MoA for 1L HR-MDS that has been permanently improved Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 531 Sponsor: AbbVie (ABBV)			Classification: False Positive (FP)
1712	Briquilimab NCTID: NCT06353971 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-ckIT mAb inhibitor Area: Immune System Diseases Indication: Chronic Inducible Urticaria Human Patients: 27 Sponsor: Jasper Therapeutics (JSPR)	Date: 31 Jul 2024 Quarter: Q3'24 Batch 21 Technical: SUCCESS (statistically significant clinical benefit in provocation threshold) Commercial: FAILURE (commercially insufficient clinical benefit in provocation threshold inferior to barzolvolimab)	Readout: 14 Jun 2025 Lead Time: 318 days in advance Interpretation: briquilimab achieved 92% CR; which is slightly inferior to the 95% CR achieved by barzolvolimab (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient (slightly inferior to barzolvolimab) Classification: True Negative (TN)
1722	SGR1505 NCTID: NCT05544019 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: allosteric MALT1 inhibitor Area: Neoplasms Indication: relapsed/refractory B-cell malignancies Human Patients: 52 Sponsor: Schrödinger (SDGR)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS)	Readout: 12 Jun 2025 Lead Time: 310 days in advance Interpretation: SGR1505 achieved a 22% ORR for median 4L+ patients	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
968	Efgartigimod NCTID: NCT05523167 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: antibody fragment biologic MoA: anti-FcRn antibody fragment Area: Immune System Diseases Indication: Active Idiopathic Inflammatory Myopathy Human Patients: 265 Sponsor: argenx (ARGX)	Date: 11 Jul 2024 Quarter: Q3'24 Batch 16 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 11 Jun 2025 Lead Time: 335 days in advance Interpretation: efgartigimod achieved 14.8 placebo-adjusted improvement in mean TIS score (50.45 vs 35.65; P=0.0004); which is below the MCID threshold (>=20 point for TIS score)	Correct Prediction Conclusion: statistically significant yet weak clinical benefit and commercially insufficient Classification: True Negative (TN)
1351	Efgartigimod NCTID: NCT05817669 Phase: Phase 2 Class: First-In-Class Modality: antibody fragment biologic MoA: anti-FcRn antibody fragment Area: Immune System Diseases Indication: Primary Sjögren's Syndrome Human Patients: 34 Sponsor: argenx (ARGX)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 4 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Jun 2025 Lead Time: 559 days in advance Interpretation: efgartigimod failed to achieve statistical significance in ESSDAI compared with placebo (-7.0 vs -4.0)	Correct Prediction Conclusion: statistically insignificant and commercially probably insufficient Classification: True Negative (TN)
436	treprostinil palmitil inhalation powder (TPIP) NCTID: NCT05147805 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: synthetic prostacyclin analog Area: Respiratory Tract Diseases Indication: Pulmonary Arterial Hypertension Human Patients: 102	Date: 1 Jan 2024 Quarter: Q1'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 10 Jun 2025 Lead Time: 526 days in advance Interpretation: TPIP achieved a 35% placebo-adjusted reduction from baseline in pulmonary vascular resistance (PVR) and 35.5 meters placebo-adjusted improvement in 6MWD (p=0.003) at week 16; slightly superior to sotatercept's 33 meters placebo-adjusted improvement in 6MWD at week 16 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Insmed Incorporated (INSM)			
1776	Navepegritide NCTID: NCT06433557 Phase: Phase 2 Class: Best-In-Class Modality: peptide MoA: long-lasting c-type natriuretic peptide Area: Musculoskeletal Diseases Indication: children with achondroplasia (ACH) Human Patients: 22 Sponsor: Ascendis Pharma (ASND)	Date: 29 Aug 2024 Quarter: Q4'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit in AGV against placebo) Commercial: SUCCESS (commercially sufficient additive clinical benefit in AGV at least numerically superior to vosoritide)	Readout: 9 Jun 2025 Lead Time: 284 days in advance Interpretation: navepegritide + lonapegsomatropin achieved 9.14cm/year mean AGV for treatment-naïve patients; superior to vosoritide's 4cm/year mean AGV for treatment-naïve patients (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)
1262	Iluzanebart (VGL101) NCTID: NCT05677659 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: TREM2 agonist Area: Nervous System Diseases Indication: Adult-Onset Leukoencephalopathy With Axonal Spheroids and Pigmented Glia Human Patients: 20 Sponsor: Vigil Neuroscience (VIGL)	Date: 12 May 2024 Quarter: Q1'25 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 4 Jun 2025 Lead Time: 388 days in advance Interpretation: Iluzanebart failed to achieve statistically significant clinical benefit in primary efficacy endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1688	SCD-044 NCTID: NCT04566666 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: highly selective second-gen S1PR1 agonist Area: Immune System Diseases Indication: Moderate to Severe Plaque Psoriasis Human Patients: 263 Sponsor: Sun Pharmaceutical (SUNPHARMA)	Date: 18 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in EASI90 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in PASI90 inferior to bimekizumab and non-superior to ustekinumab)	Readout: 2 Jun 2025 Lead Time: 319 days in advance Interpretation: SCD044 failed to achieve statistically significant clinical benefit in PASI75 compared with placebo; further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1687	SCD-044 NCTID: NCT04684485 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: highly selective second-gen S1PR1 agonist Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Atopic Dermatitis Human Patients: 250 Sponsor: Sun Pharmaceutical (SUNPHARMA)	Date: 18 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab and non-superior to baricitinib)	Readout: 2 Jun 2025 Lead Time: 319 days in advance Interpretation: SCD044 failed to achieve statistically significant clinical benefit in EASI75 compared with placebo; further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1650	177Lu-PSMA-617 NCTID: NCT04720157 Phase: Phase 3 Class: First-In-Class Modality: radionuclide drug conjugate MoA: anti-PSMA radionuclide	Date: 2 Jul 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit in rPFS) Commercial: FAILURE (commercially	Readout: 2 Jun 2025 Lead Time: 335 days in advance Interpretation: pluvicto + SoC achieved statistically significant clinical benefit in PFS compared with SoC alone; yet failed to achieve statistically significant clinical benefit	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	drug conjugates Area: Neoplasms Indication: 1L PSMA-positive metastatic hormone-sensitive prostate cancer (mHSPC) Human Patients: 1145 Sponsor: Novartis Pharmaceuticals (NVS)	insufficient additive clinical benefit in OS)	in OS compared with SoC alone	
670	LYR210 NCTID: NCT05295459 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: long-acting glucocorticoid receptor agonist Area: Respiratory Tract Diseases Indication: Chronic Rhinosinusitis Human Patients: 182 Sponsor: Lyra Therapeutics (LYRA)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 13a Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in 3CS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in 3CS)	Readout: 2 Jun 2025 Lead Time: 67 days in advance Interpretation: LYR210 achieved statistically significant clinical benefit in 3CS (-0.90; p=0.00209) and SNOT22 reduction (-8.7 p=0.0101) at week 24 in patients with/without nasal polyps; inferior to dupilumab's -14 placebo-adjusted SNOT22 reduction at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant (yet weak efficacy) and commercially probably insufficient (inferior to dupilumab) Classification: True Negative (TN)
1823	KT621 NCTID: NCT06673667 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: E3ligase-binding STAT6 degrader Area: Skin and Connective Tissue Diseases Indication: moderate-to-severe atopic dermatitis Human Patients: 120 Sponsor: Kymera Therapeutics (KYMR)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 12b Technical: partial SUCCESS (statistically significant yet weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 at most slightly superior to dupilumab and inferior to upadacitinib)	Readout: 2 Jun 2025 Lead Time: 67 days in advance Interpretation: KT621 achieved median TARC reduction up to 37% at day 14; inferior to dupilumab's 55%-65% TARC reduction at day 14 (see add'l link below)	Correct Prediction Conclusion: statistically significant (yet weak efficacy) and commercially probably insufficient (inferior to dupilumab) Classification: True Negative (TN)
1884	Atacicept NCTID: NCT04716231 Phase: Phase 3 Class: First-In-Class Modality: fusion protein biologic MoA: recombinant fusion protein anti-BAFF and anti-APRIL inhibitor Area: Immune System Diseases Indication: IgA Nephropathy Human Patients: 376 Sponsor: Vera Therapeutics (VERA)	Date: 23 Jan 2025 Quarter: Q2'25 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in UPCR compared with placebo inferior to budesonide/sparsentan/iptacopan) Commercial: FAILURE (commercially insufficient clinical benefit in eGFR inferior to budesonide/sparsentan/iptacopan)	Readout: 2 Jun 2025 Lead Time: 130 days in advance Interpretation: tacicept achieved 42% placebo-adjusted UPCR at week 36 (p<0.0001); slightly inferior to sparsentan's 45% placebo-adjusted UPCR at week 36 (using 5% UPCR reduction in the placebo group (see add'l link below); eGFR data pending)	Correct Prediction Conclusion: statistically significant (yet weak UPCR slightly inferior to sparsentan) and commercially TBD (eGFR data pending) Classification: True Negative (TN)
820	IMA203 NCTID: NCT03686124 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: autologous anti-PRAME TCR-T cell therapy Area: Neoplasms Indication: Recurrent Refractory Solid Tumors Human Patients: 476 Sponsor: Immatics (IMTX)	Date: 29 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak (additive) clinical benefit in OS)	Readout: 31 May 2025 Lead Time: 306 days in advance Interpretation: IMA203 achieved 56% cORR and 6.1 months mPFS that are moderately superior to SoC chemotherapy's 3.7 months mPFS and 10% ORR; IMA203 achieved 15.9 months mOS that's slightly superior to SoC chemotherapy's 14 months mOS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially maybe sufficient (slightly superior OS) Classification: True Positive (TP)
1981	Itepekimab NCTID: NCT04751487 Phase: Phase 3	Date: 15 May 2024 Quarter: Q3'25 Batch 1 Technical: FAILURE (statistically	Readout: 30 May 2025 Lead Time: 380 days in advance Interpretation: Itepekimab (every four	Correct Prediction Conclusion: statistically insignificant and commercially

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: monoclonal antibody MoA: IgG4P anti-IL33 inhibitor Area: Respiratory Tract Diseases Indication: Chronic Obstructive Pulmonary Disease (COPD) Human Patients: 1239 Sponsor: Sanofi (SNY)	insignificant additive clinical benefit to SoC in AECOPD/FEV1/TEAE compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in AECOPD/FEV1/TEAE inferior to mepolizumab)	weeks) + SoC achieved a statistically insignificant 12% placebo-adjusted reduction in AECOPD and -7% placebo-adjusted reduction in TEAE at week 52 compared with SoC alone; strongly inferior to mepolizumab's 21% placebo-adjusted reduction in AECOPD and 3% placebo-adjusted reduction in TEAE at week 52 compared with SoC alone (see add'l link below)	insufficient (strongly inferior to mepolizumab) Classification: True Negative (TN)
1980	Itepekimab NCTID: NCT04701983 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: IgG4P anti-IL33 inhibitor Area: Respiratory Tract Diseases Indication: Chronic Obstructive Pulmonary Disease (COPD) Human Patients: 1127 Sponsor: Sanofi (SNY)	Date: 18 Apr 2024 Quarter: Q3'25 Batch 1 Technical: FAILURE (statistically insignificant additive clinical benefit to SoC in AECOPD/FEV1/TEAE compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in AECOPD/FEV1/TEAE inferior to mepolizumab)	Readout: 30 May 2025 Lead Time: 407 days in advance Interpretation: Itepekimab (every four weeks) + SoC achieved a statistically significant 21% placebo-adjusted reduction in AECOPD and 0% placebo-adjusted reduction in TEAE at week 52 compared with SoC alone; slightly inferior to mepolizumab's 21% placebo-adjusted reduction in AECOPD and 3% placebo-adjusted reduction in TEAE at week 52 compared with SoC alone (see add'l link below)	Correct Prediction Conclusion: statistically significant (yet weak efficacy) and commercially insufficient (slightly inferior to mepolizumab) Classification: True Negative (TN)
1667	Ivonescimab NCTID: NCT06396065 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-1 and anti-VEGF Area: Neoplasms Indication: 2L advanced EGFR-mutant NSCLC Human Patients: 420 Sponsor: Summit Therapeutics (SMMT)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS non-superior to carboplatin + pemetrexed combotherapy) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to carboplatin + pemetrexed combotherapy)	Readout: 30 May 2025 Lead Time: 294 days in advance Interpretation: ivonescimab + chemotherapy achieved statistically significant clinical benefit in PFS compared with the SoC chemotherapy (HR=0.52; p<0.0001); yet failed to achieve statistically significant clinical benefit in OS compared with the SoC chemotherapy (HR=0.79 p=0.057)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1782	Patritumab Deruxtecan NCTID: NCT05338970 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-HER3 ADC conjugated with a TOP1 inhibitor payload Area: Neoplasms Indication: advanced NSCLC Human Patients: 586 Sponsor: Daiichi Sankyo Company / Merck & Co. (DSNKY/MRK)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS numerically superior to chemotherapy yet numerically inferior to BL-B01D1); partial FAILURE (statistically insignificant clinical benefit in tolerability inferior to chemotherapy yet numerically superior to BL-B01D1) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to chemotherapy yet numerically superior to BL-B01D1)	Readout: 29 May 2025 Lead Time: 262 days in advance Interpretation: patritumab deruxtecan failed to achieve statistically significant clinical benefit in OS compared with the SoC chemotherapy; and achieved 5.8 months mPFS; slightly superior to 5.6 months mPFS achieved by the SoC chemotherapy (HR = 0.77 (see add'l link below); BLA voluntarily withdrawn	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1214	Cibotercept (KER-012) NCTID: NCT05975905 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: fusion protein modified ActRIIB/ACVR2B ligand trap Area: Respiratory Tract Diseases Indication: Pulmonary Arterial Hypertension (PAH) Human Patients: 113 Sponsor: Keros Therapeutics	Date: 13 Dec 2024 Quarter: Q2'25 Batch 2 Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in PVR with on-target toxicity) Commercial: partial FAILURE (commercially maybe sufficient yet very weak additive clinical benefit in 6MWD)	Readout: 29 May 2025 Lead Time: 167 days in advance Interpretation: cibotercept's further development has been discontinued probably due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	(KROS)			
1270	Birtamimab NCTID: NCT04973137 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-mis-light-chain Area: Nutritional and Metabolic Diseases Indication: AL amyloidosis Human Patients: 220 Sponsor: Prothena Biosciences (PRTA)	Date: 14 Jul 2024 Quarter: Q4'24 Batch 11 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2025 Lead Time: 313 days in advance Interpretation: birtamimab failed to meet the primary endpoint of time to all-cause mortality or the secondary endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1672	Trodelyv (sacituzumab govitecan-hziy) NCTID: NCT05382299 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload Area: Neoplasms Indication: 1L metastatic Triple-Negative Breast Cancer (TNBC) Human Patients: 540 Sponsor: Gilead Sciences (GILD)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PFS/ORR maybe superior to chemotherapy) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to chemotherapy)	Readout: 23 May 2025 Lead Time: 318 days in advance Interpretation: trodelyv achieved statistically significant superior-to-chemotherapy clinical benefit in PFS (without disclosure of the specific data and p-value; indicating probably weak efficacy in PFS); OS data not mature yet no OS detriment was observed	Correct Prediction Conclusion: statistically probably weakly significant (PFS) and commercially TBD (pending OS data); Classification: True Negative (TN)
1462	Petosemtamab (MCLA-158) NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L R/M HNSCC Human Patients: 567 Sponsor: Merus (MRUS)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Readout: 22 May 2025 Lead Time: 463 days in advance Interpretation: petosemtamab + pembrolizumab achieved 63% ORR; 9 months mPFS; and 79% 12-month OS; superior to pembrolizumab + chemotherapy's 36% ORR; 5.8 months mPFS; and 53% 12-month OS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially sufficient (superior OS) Classification: True Positive (TP)
1773	Ficerafusp Alfa (BCA101) NCTID: NCT04429542 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody with anti-EGFR and anti-TGFBeta targets Area: Neoplasms Indication: EGFR-driven Advanced Solid Tumors Human Patients: 292 Sponsor: Bicara Therapeutics (BCAX)	Date: 26 Aug 2024 Quarter: - Batch - Technical: partial SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS numerically superior to cetuximab yet inferior to petosemtamab as monotherapy or in combination with pembrolizumab) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS inferior to chemotherapy/cetuximab/petosemtamab as monotherapy or in combination with pembrolizumab)	Readout: 22 May 2025 Lead Time: 269 days in advance Interpretation: ficerafusp alfa + pembrolizumab achieved 54% ORR; 7.4 months mPFS; and 61.5% 12-month OS (see DOI-10.1200/JCO.2025.43.16_suppl.601); inferior to petosemtamab + pembrolizumab's 63% ORR; 9 months mPFS; and 79% 12-month OS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially insufficient (inferior-to-petosemtamab OS) Classification: True Negative (TN)
1812	Avutometinib (VS-6766) NCTID: NCT05669482 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: MEK inhibitor Area: Neoplasms Indication: 1L Pancreatic Ductal Adenocarcinoma (PDAC) Human Patients: 40 Sponsor: Verastem (VSTM)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to SoC chemotherapy alone) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC chemotherapy alone)	Readout: 22 May 2025 Lead Time: 208 days in advance Interpretation: avutometinib + defactinib + gemcitabine plus nab-paclitaxel (GnP) achieved 83% ORR (10/12); superior to GnP's 63% ORR for 1L PDAC (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (PFS/OS data pending) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1617	enpatoran (M5049) NCTID: NCT05162586 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: TLR7/8 dual inhibitor Area: Immune System Diseases Indication: systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE) Human Patients: 456 Sponsor: Merck KGaA (MKKGY)	Date: 14 May 2024 Quarter: Q3'24 Batch 10 Technical: SUCCESS (statistically significant additive clinical benefit in CLASI-A for CLE and BICLA for SLE) Commercial: SUCCESS (commercially sufficient additive clinical benefit in CLASI-A for CLE and BICLA for SLE)	Readout: 21 May 2025 Lead Time: 372 days in advance Interpretation: enpatoran has met the primary endpoint for both the CLE cohort ($p=0.0002$) and predefined subpopulations in the SLE cohort	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1838	Pacibekitug (TOUR006) NCTID: NCT06362759 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL6 inhibitor Area: Urogenital Diseases Indication: Chronic Kidney Disease and Elevated High-Sensitivity C-Reactive Protein (Hs-CRP) Human Patients: 143 Sponsor: Tourmaline Bio (TRML)	Date: 9 Nov 2024 Quarter: Q1'25 Batch 9 Technical: SUCCESS (statistically significant yet moderate clinical benefit in hs-CRP reduction against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in UACR/UPCR/eGFR inferior to finerenone)	Readout: 20 May 2025 Lead Time: 192 days in advance Interpretation: pacibekitug achieved more than 70% placebo-adjusted hs-CRP $\geq 50\%$ reduction at day 90 ($p<0.0001$)	Correct Prediction Conclusion: statistically significant and commercially TBD (UACR/UPCR/eGFR data pending) Classification: True Positive (TP)
2021	PM359 NCTID: NCT06559176 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: prime-editor-mediated MCF1-delGT-mutation-corrected CD34+ autologous hematopoietic stem cells Area: Immune System Diseases Indication: Chronic Granulomatous Disease (CGD) Human Patients: 12 Sponsor: Prime Medicine (PRME)	Date: 13 May 2025 Quarter: Q3'25 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in OS/infection frequency reduction/active infection resolution/GvHD/autoimmune process frequency/active autoimmune process resolution compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in OS/infection frequency reduction/active infection resolution/GvHD/autoimmune process frequency/active autoimmune process resolution non-superior to interferon gamma)	Readout: 19 May 2025 Lead Time: 6 days in advance Interpretation: PM359's further development has been discontinued probably due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably significant and commercially probably insufficient Classification: True Negative (TN)
1313	Govorestat (AT007) NCTID: NCT05397665 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: Aldose Reductase inhibitor Area: Nervous System Diseases Indication: Hereditary Neuropathy Caused by SORD Deficiency Human Patients: 56 Sponsor: Applied Therapeutics (APLT)	Date: 2 Nov 2023 Quarter: 2H'23 Batch 27 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 18 May 2025 Lead Time: 563 days in advance Interpretation: govorestat failed to deliver statistically significant 10MWRT improvement at month 12 compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1781	ADCT-602 NCTID: NCT03698552 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: ADC MoA: anti-CD22 ADC conjugated with a PBD-dimer cytotoxin SG3249	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: SUCCESS (statistically significant clinical benefit in CR/CRi/ORR/PFS against placebo yet non-superior non-inferior to inotuzumab ozogamicin)	Readout: 14 May 2025 Lead Time: 247 days in advance Interpretation: ADCT602's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: Recurrent or Refractory B-cell Acute Lymphoblastic Leukemia (ALL) Human Patients: 57 Sponsor: ADC Therapeutics (ADCT)	Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior non-inferior to inotuzumab ozogamicin)		
1220	Aficamten NCTID: NCT05767346 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: cardiac myosin inhibitor Area: Cardiovascular Diseases Indication: Symptomatic Obstructive Hypertrophic Cardiomyopathy (oHCM) Human Patients: 175 Sponsor: Cytokinetics (CYTK)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 12b Technical: SUCCESS (statistically significant clinical benefit in pVO2-CPET and NYHA compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in pVO2-CPET and NYHA moderately superior to metoprolol succinate)	Readout: 13 May 2025 Lead Time: 47 days in advance Interpretation: aficamten achieve statistically significant clinical benefit in pVO2 compared with metoprolol	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1895	Belrestotug NCTID: NCT06472076 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-TIGIT inhibitor Area: Neoplasms Indication: PDL1 high Non-small-cell Lung Cancer (NSCLC) Human Patients: 1000 Sponsor: GlaxoSmithKline / iTeos Therapeutics (GSK / ITOS)	Date: 30 Jan 2025 Quarter: Q2'25 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit in ORR/PFS non-superior to pembrolizumab monotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS inferior to pembrolizumab monotherapy)	Readout: 13 May 2025 Lead Time: 103 days in advance Interpretation: belrestotug + dostarlimab failed to achieve statistically significant clinical benefit in PFS compared with dostarlimab mono therapy	Correct Prediction Conclusion: statistically insignificant (PFS) and commercially insufficient Classification: True Negative (TN)
1797	Soquelitinib NCTID: NCT06345404 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: anti-ITK inhibitor Area: Skin and Connective Tissue Diseases Indication: atopic dermatitis Human Patients: 64 Sponsor: Corvus Pharmaceuticals (CRVS)	Date: 10 Nov 2024 Quarter: Q1'25 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-inferior to upadacitinib)	Readout: 8 May 2025 Lead Time: 179 days in advance Interpretation: soquelitinib achieved 63% placebo-adjusted EASI75 at week 4; superior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see add'l link below); and non-inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see 10.1016/S0140-6736(21)00588-2)	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferior to upadacitinib) Classification: True Positive (TP)
1317	VCAR33 NCTID: NCT05984199 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: allogeneic anti-CD33 CAR-T cell therapy Area: Neoplasms Indication: Relapsed or Refractory AML After Allogeneic Hematopoietic Cell Transplant Human Patients: 38 Sponsor: Vor Biopharma (VOR)	Date: 7 Nov 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 8 May 2025 Lead Time: 548 days in advance Interpretation: VCAR33's further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1316	VOR33 NCTID: NCT04849910 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: cell therapy MoA: allogeneic CRISPR/CAS9	Date: 7 Nov 2023 Quarter: 2H'23 Batch 27 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit)	Readout: 8 May 2025 Lead Time: 548 days in advance Interpretation: VOR33 + mylotarg's further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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#	Clinical Trial	Certified Prediction	Validation	Result
	genome-edited anti-CD33 HSPC cell therapy VOR33 + anti-CD33 ADC mylotarg Area: Neoplasms Indication: CD33+ acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) Human Patients: 67 Sponsor: Vor Biopharma (VOR)	Commercial: FAILURE (commercially insufficient additive clinical benefit)		
557	PTC518 NCTID: NCT05358717 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: HTT mRNA degradation Area: Nervous System Diseases Indication: Huntington's Disease Human Patients: 252 Sponsor: PTC Therapeutics (PTCT)	Date: 5 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in lowering tHTT level) Commercial: FAILURE (commercially insufficient clinical benefit in UHDRS-TFC score)	Readout: 5 May 2025 Lead Time: 426 days in advance Interpretation: PTC518 failed to deliver statistically significant improvement in the efficacy endpoint cUHDRS at month 12	Correct Prediction Conclusion: statistically significant (mHTT) and commercially insufficient (UHDRS) Classification: True Negative (TN)
1240	Eftilagimod alpha NCTID: NCT04811027 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: a Soluble LAG-3 Fusion Protein Area: Neoplasms Indication: Recurrent or Metastatic HNSCC Human Patients: 171 Sponsor: Immute (IMMP)	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 5 May 2025 Lead Time: 609 days in advance Interpretation: efti + pembrolizumab achieved 17.6 months mOS; superior to 10.7 months mOS achieved by cetuximab + chemotherapy or 11.3 months mOS achieved by anti-PD1 therapy + chemotherapy	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1592	REC-2282 NCTID: NCT05130866 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: HDAC inhibitor Area: Neoplasms Indication: Progressive Neurofibromatosis Type 2 (NF2) Mutated Meningiomas Human Patients: 92 Sponsor: Recursion Pharmaceuticals (RXRX)	Date: 11 May 2024 Quarter: Q4'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-microsurgery/radiosurgery efficacy)	Readout: 5 May 2025 Lead Time: 359 days in advance Interpretation: REC2282 failed to achieve statistically significant improvement in efficacy whose further development has thus been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1591	REC-994 NCTID: NCT05085561 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: superoxide dismutase small molecule mimetic Area: Nervous System Diseases Indication: Cerebral Cavernous Malformation (CCM) Human Patients: 62 Sponsor: Recursion Pharmaceuticals (RXRX)	Date: 11 May 2024 Quarter: Q3'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit with a negative dose-response relationship) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-microsurgery/radiosurgery efficacy)	Readout: 5 May 2025 Lead Time: 359 days in advance Interpretation: REC994 failed to achieve statistically significant improvement in efficacy whose further development has thus been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1818	REC-4881 NCTID: NCT05552755 Phase: Phase 1 Phase 2 Class: First-In-Class	Date: 3 Nov 2024 Quarter: Q1'25 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet	Readout: 4 May 2025 Lead Time: 182 days in advance Interpretation: REC4881 achieved a median 43% reduction in polyp	Correct Prediction Conclusion: statistically probably significant and commercially probably sufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule MoA: oral non-ATP-competitive MEK1/MEK2 inhibitor Area: Neoplasms Indication: Familial Adenomatous Polyposis (FAP) Human Patients: 67 Sponsor: Recursion Pharmaceuticals (RXRX)	moderate clinical benefit in polyp burden at week 12 against placebo with a positive duration-response relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in in polyp burden at week 24 superior to celecoxib)	burden at week 13; superior to celecoxib's 28% reduction in polyp burden at week 24 (see add'l link below)	Classification: True Positive (TP)
1963	BREZTRI (PT010) NCTID: NCT04609904 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: triple-combination inhaler therapy of budesonide; glycopyrronium; and formoterol fumarate Area: Respiratory Tract Diseases Indication: Inadequately Controlled Severe Asthma Human Patients: 2187 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: SUCCESS (statistically significant clinical benefit in FEV1 moderately superior to PT009/Symbicort) Commercial: SUCCESS (commercially sufficient clinical benefit in annualized rate of severe asthma exacerbation moderately superior to PT009/Symbicort; slightly superior to dupilumab; and non-superior-non-inferior to tezepelumab)	Readout: 2 May 2025 Lead Time: 21 days in advance Interpretation: BREZTRI achieved statistically significant improvement in annualized rate of severe asthma exacerbation; superior to the ICS/LABA SoC treatment	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1962	BREZTRI (PT010) NCTID: NCT04609878 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: triple-combination inhaler therapy of budesonide; glycopyrronium; and formoterol fumarate Area: Respiratory Tract Diseases Indication: Inadequately Controlled Severe Asthma Human Patients: 2274 Sponsor: AstraZeneca (AZN)	Date: 11 Apr 2025 Quarter: Q2'25 Batch 14d Technical: SUCCESS (statistically significant clinical benefit in FEV1 moderately superior to PT009/Symbicort) Commercial: SUCCESS (commercially sufficient clinical benefit in annualized rate of severe asthma exacerbation moderately superior to PT009/Symbicort; slightly superior to dupilumab; and non-superior-non-inferior to tezepelumab)	Readout: 2 May 2025 Lead Time: 21 days in advance Interpretation: BREZTRI achieved statistically significant improvement in annualized rate of severe asthma exacerbation; superior to the ICS/LABA SoC treatment	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1868	IMU-838 NCTID: NCT05054140 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: DHODH inhibitor and NURR1 activator Area: Nervous System Diseases Indication: Progressive Multiple Sclerosis (PMS) Human Patients: 450 Sponsor: Immunic (IMUX)	Date: 14 Jan 2025 Quarter: Q2'25 Batch 2 Technical: FAILURE (statistically insignificant clinical benefit in EDSS/CDP compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EDSS/CDP inferior to tolebrutinib)	Readout: 30 Apr 2025 Lead Time: 106 days in advance Interpretation: IMU838 failed to achieve statistically significant EDSS improvement compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1827	XmAb942 NCTID: NCT06619990 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-TL1A inhibitor Area: Immune System Diseases Indication: Ulcerative Colitis Human Patients: 300 Sponsor: Xencor (XNCR)	Date: 22 Jan 2025 Quarter: Q2'25 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit in MMS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in MMS inferior to PRA023/TEV574)	Readout: 29 Apr 2025 Lead Time: 97 days in advance Interpretation: XmAb942 achieved a half-life estimate of greater than 71 days and sufficient tolerability	Correct Prediction Conclusion: statistically significant (tolerability) and commercially TBD Classification: True Positive (TP)
1093	Evorpcept (ALX148) NCTID: NCT04675294 Phase: Phase 2 Class: First-In-Class	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L	Readout: 25 Apr 2025 Lead Time: 304 days in advance Interpretation: evorpcept + SoC failed to achieve statistically	Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: fusion protein biologic MoA: CD47 blocker Area: Neoplasms Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) Human Patients: 189 Sponsor: ALX Oncology (ALXO)	treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS non-superior to pembrolizumab + chemotherapy)	significant clinical benefit in ORR/PFS/OS compared with SoC alone	Classification: True Negative (TN)
1092	Evorpaccept (ALX148) NCTID: NCT04675333 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: CD47 blocker Area: Neoplasms Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) Human Patients: 172 Sponsor: ALX Oncology (ALXO)	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS non-superior to pembrolizumab + chemotherapy)	Readout: 25 Apr 2025 Lead Time: 304 days in advance Interpretation: evorpaccept + SoC failed to achieve statistically significant clinical benefit in ORR/PFS/OS compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1857	Amlitelimab NCTID: NCT06118099 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-OX40L inhibitor Area: Immune System Diseases Indication: Moderate to Severe Hidradenitis Suppurativa Human Patients: 90 Sponsor: Sanofi (SNY)	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in HiSCR50 score against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in HiSCR50 score non-superior to adalimumab/povorcitinib and inferior to SAR442970/sonelokimab/bimekizumab/secukinumab)	Readout: 24 Apr 2025 Lead Time: 138 days in advance Interpretation: amlitelimab's HiSCR50 is inferior to brivekimig (SAR442970)'s HiSCR50; so amlitelimab further development is discontinued	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1973	Balinatunfib NCTID: NCT06073119 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: TNFalpha inhibitor Area: Immune System Diseases Indication: moderate to severe plaque psoriasis Human Patients: 221 Sponsor: Sanofi (SNY)	Date: 18 Apr 2025 Quarter: Q3'25 Batch 1 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit in PASI75 compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in PASI75/PASI90 moderately inferior to bimekizumab/ixekizumab and slightly inferior to icotrokinra)	Readout: 24 Apr 2025 Lead Time: 6 days in advance Interpretation: balinatunfib failed to achieve the primary endpoint of PASI75 at week 12	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1958	Adjunctive KarXT NCTID: NCT05145413 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: fixed-dose combination of xanomeline and trospium chloride KarXT Area: Nervous System Diseases Indication: treatment-resistant schizophrenia Human Patients: 396 Sponsor: Bristol-Myers Squibb (BMS)	Date: 2 Apr 2025 Quarter: Q2'25 Batch 14b Technical: SUCCESS (statistically significant additive clinical benefit in PANSS compared with placebo) Commercial: SUCCESS (commercially sufficient additive clinical benefit in PANSS moderately superior to lumateperone)	Readout: 22 Apr 2025 Lead Time: 20 days in advance Interpretation: KarXT + SoC failed to deliver additional clinical benefit in PANSS total score at week 6 compared with SoC alone	Missed Prediction Note: due to suboptimal disease modelling of schizophrenia not uncontrollable by standard therapies; whic... Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1948	Orforglipron NCTID: NCT05971940 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: once-daily oral GLP1R agonist	Date: 30 Mar 2025 Quarter: Q2'25 Batch 13b Technical: SUCCESS (statistically significant clinical benefit in HbA1c and weight reduction compared with placebo)	Readout: 15 Apr 2025 Lead Time: 16 days in advance Interpretation: orforglipron 36mg achieved 6.3% placebo-adjusted weight reduction and 1.4% placebo-adjusted HbA1c reduction at week 40; which is numerically	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-superior-non-inferior to semaglutide 2.4mg) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Nutritional and Metabolic Diseases Indication: type 2 diabetes Human Patients: 559 Sponsor: Eli Lilly and Company (LLY)	Commercial: SUCCESS (commercially sufficient clinical benefit as an oral therapy in HbA1c and weight reduction non-superior-non-inferior to semaglutide/GSBR1290 with numerically inferior-to-semaglutide tolerability)	superior to semaglutide 2.4mg's 6.2% placebo-adjusted weight reduction and 1.2% placebo-adjusted HbA1c reduction at week 40 (see add'l link below) orforglipron 36mg achieved 7% placebo-adjusted adverse-effect-caused discontinuation rate; slightly inferior to semaglutide 2.4mg's 5% placebo-adjusted adverse-effect-caused discontinuation rate	
1757	Amltelimab NCTID: NCT05421598 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-OX40L inhibitor Area: Respiratory Tract Diseases Indication: Moderate-to-severe Asthma Human Patients: 446 Sponsor: Sanofi (SNY)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in annualized rate of severe exacerbation) Commercial: SUCCESS (commercially sufficient additive clinical benefit in FEV1/ACQ5)	Readout: 14 Apr 2025 Lead Time: 238 days in advance Interpretation: amltelimab failed to meet the primary endpoint of annualized exacerbation rate at week 48	Missed Prediction Note: due to suboptimal disease modelling of asthma not uncontrollable by background therapies that have ... Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1755	Danuglipron NCTID: NCT06153758 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: once-daily oral GLP1R1 agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 33 Sponsor: Pfizer (PFE)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 11 Technical: partial SUCCESS (statistically significant clinical benefit in weight reduction for healthy obese patients against placebo despite being at least numerically inferior to orforglipron/GSBR1290) Commercial: partial SUCCESS (commercially sufficient clinical benefit in muscle retention and cardio protection for healthy obese patients at least numerically superior to orforglipron/GSBR1290)	Readout: 14 Apr 2025 Lead Time: 242 days in advance Interpretation: danuglipron discontinued further development based on the totality of efficacy and toxicity information; thus at least inferior to orforglipron	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1830	VERVE102 NCTID: NCT06164730 Phase: Phase 1 Class: First-In-Class Modality: gene therapy MoA: LNP-delivered GalNAc-conjugated anti-PCSK9 base editing gene therapy Area: Nutritional and Metabolic Diseases Indication: heterozygous familial hypercholesterolemia (HeFH) and/or premature coronary artery disease (CAD) Human Patients: 36 Sponsor: Verve Therapeutics (VERV)	Date: 9 Nov 2024 Quarter: Q1'25 Batch 8 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit in lowering LDL-C) Commercial: FAILURE (commercially insufficient clinical benefit in lowering LDL-C due to non-superior-to-SoC efficacy and inferior-to-SoC toxicity; despite the superiority of VERVE-102 over VERVE-101)	Readout: 14 Apr 2025 Lead Time: 156 days in advance Interpretation: VERVE102 achieved a mean reduction in blood LDL-C of 53% without any SAEs; which is inferior to the 76% LDL-C reduction achieved by evolocumab (see add'l link below); and superior to VERVE101 that has one grade 3 TEAE	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1959	Mavacamten NCTID: NCT05582395 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: cardiac myosin inhibitor Area: Cardiovascular Diseases Indication: non-obstructive hypertrophic cardiomyopathy (nHCM) Human Patients: 580 Sponsor: Bristol-Myers Squibb (BMY)	Date: 2 Apr 2025 Quarter: Q2'25 Batch 14b Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in KCCQ compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in KCCQ moderately inferior to aficamten)	Readout: 14 Apr 2025 Lead Time: 12 days in advance Interpretation: mavacamten failed to meet either the KCCQ-23 CSS or the pVO2 primary endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
1332	Setmelanotide NCTID: NCT05774756 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: MC4R agonist Area: Nutritional and Metabolic Diseases Indication: Acquired Hypothalamic Obesity Human Patients: 120 Sponsor: Rhythm Pharmaceuticals (RYTM)	Date: 20 Nov 2023 Quarter: Q1'25 Batch 8 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 7 Apr 2025 Lead Time: 504 days in advance Interpretation: setmelanotide achieved a 19.8% placebo-adjusted difference in BMI reduction at week 52 (p<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1195	Tovecimig (CTX009) NCTID: NCT05506943 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody that inhibits both DLL4 and VEGF-A Area: Neoplasms Indication: advanced billiard tract cancers Human Patients: 150 Sponsor: Compass Therapeutics (CMPX)	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to paclitaxel monotherapy regardless of DLL4 baseline expression) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit in OS superior to paclitaxel monotherapy for high-DLL4-baseline-expression patients) partial FAILURE (commercially insufficient additive clinical benefit in OS non-superior to paclitaxel monotherapy for low-DLL4-baseline-expression patients)	Readout: 1 Apr 2025 Lead Time: 149 days in advance Interpretation: tovecimig + paclitaxel achieved 17.1% ORR superior to 5.3% ORR for paclitaxel alone (p=0.031); PFS and OS data not mature yet	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (OS pending) Classification: True Positive (TP)
552	Relacorilant NCTID: NCT05257408 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral non-steroidal glucocorticoid receptor antagonist Area: Neoplasms Indication: platinum-resistant ovarian cancer Human Patients: 381 Sponsor: Concept Therapeutics (CORT)	Date: 14 Apr 2024 Quarter: Q4'24 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 31 Mar 2025 Lead Time: 351 days in advance Interpretation: relacorilant + chemotherapy achieved statistical significance in both PFS improvement (HR=0.70 p=0.008) and OS improvement (HR=0.69 p=0.012) compared with chemotherapy alone	Missed Prediction Note: due to suboptimal indication-specific glucocorticoid receptor modelling that has been permanently i... Conclusion: statistically significant and commercially sufficient Classification: False Negative (FN)
705	muvalaplin NCTID: NCT05565742 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: anti-Lp(a) inhibitor Area: Cardiovascular Diseases Indication: atherosclerotic cardiovascular disease Human Patients: 216 Sponsor: Eli Lilly and Company (LLY)	Date: 21 Aug 2022 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 30 Mar 2025 Lead Time: 952 days in advance Interpretation: lepodisiran met the primary endpoint by achieving a 93.9% placebo-adjusted reduction in Lp(a) levels with the highest tested dose (400mg)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1531	Semaglutide NCTID: NCT04560998 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Cardiovascular Diseases Indication: type 2 diabetes and peripheral artery disease	Date: 24 Mar 2024 Quarter: Q2'24 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 29 Mar 2025 Lead Time: 370 days in advance Interpretation: semaglutide achieved a 13% placebo-adjusted improvement in maximum walking distance (p=0.0004) and 39.9 meter step incline walking distance improvement at week 52	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 792 Sponsor: Novo Nordisk (NVO)			
1392	Lorundrostat NCTID: NCT05769608 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: aldosterone synthase inhibitor Area: Cardiovascular Diseases Indication: uncontrolled hypertension Human Patients: 285 Sponsor: Mineralys Therapeutics (MLYS)	Date: 26 Jul 2024 Quarter: Q1'25 Batch 4 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in ABPM SBP with a negative dose-response relationship) Commercial: FAILURE (commercially insufficient additive clinical benefit in AOBP SBP for the mixed uncontrolled/resistant hypertension patients without further resistance/biomarker-based stratifications; as we predict that lorundrostat (which is non-inferior non-superior to baxdrostat) could deliver commercially sufficient additive clinical benefit only for either resistant hypertension patients or uncontrolled hypertension patients featuring aberrant plasma aldosterone level/aldosterone-to-renin ratio)	Readout: 29 Mar 2025 Lead Time: 246 days in advance Interpretation: lorundrostat achieved 7.9mmHg (50mg p=0.001) or 6.4mmHg (50-100mg p=0.006) placebo-adjusted 24hr ABPM reduction at week 12 featuring a negative dose-response relationship; which is non-superior to 6-12 mmHg placebo-adjusted 24hr ABPM reduction achieved by adding a third therapy to two standard anti-hypertension medications (see add'l link below)	Correct Prediction Conclusion: statistically significant (yet weak efficacy) and commercially insufficient Classification: True Negative (TN)
847	Itolizumab NCTID: NCT05263999 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD6 inhibitor Area: Immune System Diseases Indication: Acute Graft Versus Host Disease (aGVHD) Human Patients: 158 Sponsor: Equillum (EQ)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant yet moderate additive clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient additive clinical benefit)	Readout: 27 Mar 2025 Lead Time: 403 days in advance Interpretation: itolizumab + corticosteroids met several key secondary endpoints (CR) at day 99 yet failed to meet primary endpoint (CR) at day 29 compared with corticosteroids monotherapy	Correct Prediction Conclusion: statistically partially significant and commercially maybe sufficient Classification: True Negative (TN)
971	Amivantamab NCTID: NCT04487080 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody anti-EGFR and anti-MET inhibitor Area: Neoplasms Indication: EGFR-mutant Non-Small Cell Lung Cancer (NSCLC) Human Patients: 1074 Sponsor: Johnson & Johnson (JNJ)	Date: 5 Apr 2023 Quarter: Q2'2023 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (non-superior)	Readout: 26 Mar 2025 Lead Time: 721 days in advance Interpretation: amivantamab + lazertinib achieve statistically significant clinical benefit in mOS (H R = 0.75 p < 0.005) compared to osimertinib; In contrast amivantamab + lazertinib has 12% grade ≥3 SAE; inferior to 1% grade ≥3 SAE for osimertinib; The overall clinical benefit of amivantamab + lazertinib is grade 1 negligible (according to ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 2A (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (negligible OS benefit) Classification: True Negative (TN)
1725	Simufilam NCTID: NCT05026177 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: FLNA inhibitor Area: Nervous System Diseases Indication: Mild-to-Moderate Alzheimer's Disease Human Patients: 1125 Sponsor: Cassava Sciences (SAVA)	Date: 6 Aug 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ADAS-COG12/ADCS-ADL23 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in ADAS-COG12/ADCS-ADL23 inferior to lecanemab)	Readout: 25 Mar 2025 Lead Time: 231 days in advance Interpretation: simufilam failed to meet primary efficacy endpoints ADAS-COG12 and ADCS-ADL at week 76	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1814	MRT-6160	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4	Readout: 20 Mar 2025 Lead Time: 137 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT06597799 Phase: Phase 1 Class: First-In-Class Modality: molecular glue degrader MoA: anti-VAV1 molecular glue degrader Area: Immune System Diseases Indication: autoimmune diseases Human Patients: 76 Sponsor: Monte Rosa Therapeutics (GLUE)	Technical: SUCCESS (statistically significant clinical benefit against placebo for certain treatment-naïve and treatment-refractory autoimmune diseases) Commercial: SUCCESS (commercially sufficient clinical benefit for certain treatment-naïve and treatment-refractory autoimmune diseases superior to the corresponding SoCs)	Interpretation: MRT6160 achieved >90% VAV1 degradation	Conclusion: statistically significant (safety) and commercially TBD Classification: True Positive (TP)
1249	MRT-2359 NCTID: NCT05546268 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: molecular glue degrader MoA: anti-GSPT1 molecular glue degrader Area: Neoplasms Indication: MYC-driven advanced solid tumours Human Patients: 174 Sponsor: Monte Rosa Therapeutics (GLUE)	Date: 30 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically maybe significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Mar 2025 Lead Time: 537 days in advance Interpretation: MRT2359 achieved 8% ORR (1/13) for MYC-positive patients and 3% ORR (1/37) for all patients; further development in SCLC; NSCLC; NE tumors discontinued due to low efficacy except for AR-resistant CRPC	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1658	OAV101 (AVXS-101) NCTID: NCT05089656 Phase: Phase 3 Class: First-In-Class Modality: gene therapy MoA: rAAV9-mediated gene therapy with SMN1 transgene Area: Nervous System Diseases Indication: Type 2 Spinal Muscular Atrophy (SMA) Human Patients: 127 Sponsor: Novartis Pharmaceuticals (NVS)	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in HFMSE at week 52) Commercial: FAILURE (commercially insufficient clinical benefit in HFMSE at week 52 inferior to nusinersen)	Readout: 19 Mar 2025 Lead Time: 261 days in advance Interpretation: OAV101 achieved 1.88 point placebo-adjusted improvement in HFMSE score (p=0.0074); inferior to nusinersen's 4.9 point placebo-adjusted improvement in HFMSE score (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient (1.88 point is below the 3-point minimal threshold of clinically meaningful improvement in HFMSE score (DOI -10.1007/s40120-024-00653-2)) Classification: True Negative (TN)
1166	Batoclimab NCTID: NCT05581199 Phase: Phase 2 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-FcRn mAb inhibitor Area: Immune System Diseases Indication: Active Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Human Patients: 277 Sponsor: Immunovant Sciences (IMVT)	Date: 19 Oct 2024 Quarter: Q1'25 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit non-superior to efgartigimod)	Readout: 19 Mar 2025 Lead Time: 151 days in advance Interpretation: batoclimab achieved 81% responder rate at week 12 for patients whose IgG was 70%; whereas efgartigimod achieved 67% responder rate at week 12 for all patients regardless of IgG reduction levels; no plan to seek regulatory approval for marketing batoclimab	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: True Negative (TN)
1162	Batoclimab NCTID: NCT05403541 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-FcRn mAb inhibitor Area: Immune System Diseases Indication: generalized myasthenia gravis (gMG) Human Patients: 240 Sponsor: Immunovant Sciences (IMVT)	Date: 19 Oct 2024 Quarter: Q1'25 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit non-superior to efgartigimod)	Readout: 19 Mar 2025 Lead Time: 151 days in advance Interpretation: batoclimab achieved 2 placebo-adjusted MG-ADL score reduction at week 12 (p < 0.001); numerically superior to efgartigimod's 1.6-1.7 placebo-adjusted MG-ADL score reduction at week 8-11 (see add'l link below) no plan to seek regulatory approval for marketing batoclimab	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1811	Povorcitinib (INCB054707) NCTID: NCT05620836 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: JAK1 inhibitor Area: Immune System Diseases Indication: Moderate to Severe Hidradenitis Suppurativa Human Patients: 619 Sponsor: Incyte Corporation (INCY)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant yet moderate clinical benefit in HiSCR50 score against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in HiSCR50 score non-superior to adalimumab and inferior to sonelokimab/bimekizumab/secukinumab)	Readout: 17 Mar 2025 Lead Time: 142 days in advance Interpretation: povorcitinib has achieved a 13.7% placebo-adjusted HiSCR50; non-superior to 15.6%-31.3% placebo-adjusted HiSCR50 achieved by adalimumab (DOI-10.1056/NEJMoa1504370) and inferior to 22% placebo-adjusted HiSCR50 achieved by bimekizumab (see add'l link below)	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1810	Povorcitinib (INCB054707) NCTID: NCT05620823 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: JAK1 inhibitor Area: Immune System Diseases Indication: Moderate to Severe Hidradenitis Suppurativa Human Patients: 608 Sponsor: Incyte Corporation (INCY)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant yet moderate clinical benefit in HiSCR50 score against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in HiSCR50 score non-superior to adalimumab and inferior to sonelokimab/bimekizumab/secukinumab)	Readout: 17 Mar 2025 Lead Time: 142 days in advance Interpretation: povorcitinib has achieved a 10.9% placebo-adjusted HiSCR50; non-superior to 15.6%-31.3% placebo-adjusted HiSCR50 achieved by adalimumab (DOI-10.1056/NEJMoa1504370) and inferior to 22% placebo-adjusted HiSCR50 achieved by bimekizumab (see add'l link below)	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1864	Eneboparatide (AZP-3601) NCTID: NCT05778071 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: PTH1R agonist Area: Endocrine System Diseases Indication: Chronic Hypoparathyroidism (HypoPT) Human Patients: 165 Sponsor: AstraZeneca (AZN)	Date: 12 Dec 2024 Quarter: Q1'25 Batch 13b Technical: SUCCESS (statistically significant clinical benefit in the composite endpoint compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in both supplement independence and hypercalciuria)	Readout: 17 Mar 2025 Lead Time: 95 days in advance Interpretation: eneboparatide has met the composite primary endpoint	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1000	AOC1044 (del-zota) NCTID: NCT05670730 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: antibody-conjugated antisense oligonucleotide ASO MoA: antibody-oligonucleotide conjugate that binds the transferrin receptor 1 (TfR1) to deliver a PMO into muscle cells; inducing exon 44 skipping restoring functional dystrophin synthesis Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 70 Sponsor: Avidity Biosciences (RNA)	Date: 7 Jul 2024 Quarter: Q3'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in dystrophin protein level) Commercial: FAILURE (commercially insufficient clinical benefit in the registrational endpoint 6MWD non-superior and non-inferior to DYNE251 or SRP5051)	Readout: 17 Mar 2025 Lead Time: 253 days in advance Interpretation: del-zota achieved a statistically significant increase of 25% dystrophin production and 40% in exon 44 skipping; 6MWD data immature	Correct Prediction Conclusion: statistically significant (dystrophin) and commercially TBD (6MWD) Classification: True Positive (TP)
1836	Luveltamab Tazevibulin NCTID: NCT06555263 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-FOLR1 ADC conjugated with SC209 payload Area: Neoplasms Indication: Advanced or Metastatic Non-small Cell Lung	Date: 9 Nov 2024 Quarter: Q1'25 Batch 9 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially sufficient clinical benefit in OS inferior to SoC)	Readout: 13 Mar 2025 Lead Time: 124 days in advance Interpretation: luvelta's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Cancer (NSCLC) Human Patients: 43 Sponsor: Sutro Biopharma (STRO)			
1424	Vepdegestrant NCTID: NCT05909397 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: PROTAC-based ER degrader Area: Neoplasms Indication: 1L ER+HER2-advanced breast cancer Human Patients: 59 Sponsor: Arvinas / Pfizer (ARVN / PFE)	Date: 15 Jan 2024 Quarter: Q1'24 bespoke Batch Q1'24 bespoke Technical: partial SUCCESS (statistically maybe significant additive clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit non-superior-to Letrozole as 1L treatment)	Readout: 11 Mar 2025 Lead Time: 421 days in advance Interpretation: vepdegestrant + palbociclib's further development has been discontinued probably due to uncompetitive clinical benefit compared with vepdegestrant + atimociclib	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1423	Vepdegestrant NCTID: NCT05654623 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: PROTAC-based ER degrader Area: Neoplasms Indication: ER+HER2- advanced breast cancer Human Patients: 624 Sponsor: Arvinas / Pfizer (ARVN / PFE)	Date: 15 Jan 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit as 2L treatment) Commercial: SUCCESS (commercially sufficient clinical benefit superior to fulvestrant as 2L treatment)	Readout: 11 Mar 2025 Lead Time: 421 days in advance Interpretation: vepdegestrant met the primary endpoint in PFS (HR < 0.60) for ESR1m population but not the ITT population; OS data not mature	Missed Prediction Note: tentatively missed prediction for PFS only ; ultimately could still be correct prediction should OS... Conclusion: statistically insignificant (PFS) and commercially TBD Classification: False Positive (FP)
1673	HexaBody-CD38 (GEN3014) NCTID: NCT04824794 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD38 mAb with Fc-domain-specific E430G mutation Area: Neoplasms Indication: relapsed or refractory multiple myeloma (RRMM) Human Patients: 130 Sponsor: Genmab / Johnson & Johnson (GMAB / JNJ)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit in PFS/ORR superior to daratumumab for RRMM) Commercial: SUCCESS (commercially sufficient clinical benefit in CR/OS superior to daratumumab for RRMM)	Readout: 10 Mar 2025 Lead Time: 244 days in advance Interpretation: GEN3014 achieved 55% ORR and 7% CR; superior to 52% ORR and 2% CR achieved by the daratumumab arm	Correct Prediction Conclusion: statistically significant (ORR) and commercially probably sufficient (CR) Classification: True Positive (TP)
794	ARO-C3 NCTID: NCT05083364 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: siRNA-GalNAc conjugate that suppresses APOC3 mRNA Area: Immune System Diseases Indication: IgA nephropathy Human Patients: 62 Sponsor: Arrowhead Pharmaceuticals (ARWR)	Date: 14 Feb 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 10 Mar 2025 Lead Time: 390 days in advance Interpretation: ARO-C3 achieved 87% C3 reduction; 89% UPCR reduction at week 24 without SAEs	Correct Prediction Conclusion: statistically probably significant and commercially TBD (pending eGFR data) Classification: True Positive (TP)
1869	icotrokinra (JNJ-2113) NCTID: NCT06049017 Phase: Phase 2 Class: First-In-Class Modality: peptide	Date: 14 Jan 2025 Quarter: Q2'25 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in clinical response/remission compared with	Readout: 10 Mar 2025 Lead Time: 55 days in advance Interpretation: icotrokinra achieved 20.1% placebo-adjusted clinical remission rate at week 12 (p<0.001);	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to PRA023)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: anti-IL23R antagonist Area: Immune System Diseases Indication: Moderately to Severely Active Ulcerative Colitis Human Patients: 252 Sponsor: Johnson & Johnson / Protagonist Therapeutics (JNJ / PTGX)	placebo) Commercial: FAILURE (commercially insufficient clinical benefit in clinical response/remission)	inferior to PRA023 (tulisokibart) that achieved 25% placebo-adjusted clinical remission rate at week 12 for UC patients (see add'l link below)	Classification: True Negative (TN)
1394	Lorundrostat NCTID: NCT06153693 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: aldosterone synthase inhibitor Area: Cardiovascular Diseases Indication: Uncontrolled and Resistant Hypertension Human Patients: 1083 Sponsor: Mineralys Therapeutics (MLYS)	Date: 26 Jul 2024 Quarter: Q1'25 Batch 4 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in AOBP SBP with a negative dose-response relationship) Commercial: partial SUCCESS (commercially maybe sufficient additive clinical benefit in AOBP SBP for the mixed uncontrolled/resistant hypertension patients possibly with poorly controlled obesity/diabetes without further resistance/biomarker-based stratifications; as we predict that lorundrostat (which is non-inferior non-superior to baxdrostat) could deliver commercially sufficient additive clinical benefit only for either resistant hypertension patients or uncontrolled hypertension patients featuring aberrant plasma aldosterone level/aldosterone-to-renin ratio)	Readout: 10 Mar 2025 Lead Time: 227 days in advance Interpretation: lorundrostat achieved 9.1mmHg (50mg p <0.0001; 50-100mg insignificant) placebo-adjusted AOBP reduction at week 6 featuring a negative dose-response relationship	Correct Prediction Conclusion: statistically significant and commercially sufficient for mix patients Classification: True Positive (TP)
1518	CagriSema NCTID: NCT05394519 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: combo amylin analog + GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Overweight Obesity Type 2 Diabetes Mellitus Human Patients: 1200 Sponsor: Novo Nordisk (NVO)	Date: 31 Jan 2025 Quarter: Q1'25 Batch 13c Technical: SUCCESS (statistically significant clinical benefit in HbA1c and weight reduction compared with placebo yet featuring negative morbidity-response relationship and negative age-response relationship for obese T2DM patients) Commercial: FAILURE (commercially insufficient clinical benefit in HbA1c and weight reduction at most numerically superior to semaglutide for obese T2DM patients)	Readout: 10 Mar 2025 Lead Time: 38 days in advance Interpretation: CagriSema achieved 10.3% placebo-adjusted weight loss at week 68; which is superior to semaglutide that achieved 6.2% placebo-adjusted weight loss at week 68 (DOI-10.1016/S0140-6736(21)00213-0); yet inferior to tirzepatide achieved 12.2% placebo-adjusted weight loss at week 68 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient (superior to semaglutide yet inferior to tirzepatide) Classification: True Negative (TN)
1860	Rocatinlimab NCTID: NCT05724199 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-OX40 inhibitor Area: Skin and Connective Tissue Diseases Indication: Moderate-to-sever Atopic Dermatitis Human Patients: 746 Sponsor: Amgen (AMGN)	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit in vIGA-AD/EASI75 against placebo with positive dose-response relationship) Commercial: partial SUCCESS (commercially sufficient yet moderate additive clinical benefit in vIGA-AD/EASI75 (higher dose); superior to dupilumab +TCS/TCI yet inferior to upadacitinib +TCS/TCI)	Readout: 8 Mar 2025 Lead Time: 91 days in advance Interpretation: rocatinlimab (low dose) achieved 30.4% placebo-adjusted EASI75 at week 24; inferior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see 10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (inferior to upadacitinib) Classification: True Negative (TN)
1859	Rocatinlimab NCTID: NCT05398445 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-OX40 inhibitor Area: Skin and Connective	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in vIGA-AD/EASI75 against placebo with positive dose-response relationship)	Readout: 8 Mar 2025 Lead Time: 91 days in advance Interpretation: rocatinlimab achieved 29.5% placebo-adjusted EASI75 at week 24; inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially maybe insufficient (inferior to upadacitinib) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Tissue Diseases Indication: Moderate-to-sever Atopic Dermatitis Human Patients: 769 Sponsor: Amgen (AMGN)	Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in vIGA-AD/ EASI75 (higher dose); superior to dupilumab yet inferior to upadacitinib)		
1586	Ompenaclid NCTID: NCT05983367 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: SLC6A8 inhibitor Area: Neoplasms Indication: 2L RAS-mutant Metastatic Colorectal Cancer (mCRC) Human Patients: 70 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit to bevacizumab + chemotherapy in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit to bevacizumab + chemotherapy in OS)	Readout: 7 Mar 2025 Lead Time: 303 days in advance Interpretation: ompenaclid received negative topline data and discontinued further development	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1506	Aticaprant NCTID: NCT05550532 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective KOR antagonist Area: Mental Disorders Indication: Major Depressive Disorder (MDD) Human Patients: 444 Sponsor: Johnson & Johnson (JNJ)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit inferior to quetiapine or lumateperone)	Readout: 6 Mar 2025 Lead Time: 353 days in advance Interpretation: aticaprant discontinued further development due to insufficient efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1430	Aticaprant NCTID: NCT05455684 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective KOR antagonist Area: Mental Disorders Indication: Major Depressive Disorder (MDD) Human Patients: 513 Sponsor: Johnson & Johnson (JNJ)	Date: 19 Jan 2024 Quarter: Q2'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit inferior to quetiapine or lumateperone)	Readout: 6 Mar 2025 Lead Time: 412 days in advance Interpretation: aticaprant discontinued further development due to insufficient efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1015	Rusfertide NCTID: NCT05210790 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: peptide mimetic of hepcidin Area: Neoplasms Indication: Polycythemia Vera (PV) Human Patients: 250 Sponsor: Protagonist Therapeutics (PTGX)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in phlebotomy eligibility superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit in PROMIS Short Form score superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib)	Readout: 3 Mar 2025 Lead Time: 128 days in advance Interpretation: rusfertide as an add-on treatment has met both the primary endpoint with 44% placebo-adjusted improvement in clinical response rate (p<0.0001) and four key secondary endpoints (phlebotomy/hematocrit control/PROMIS Fatigue SF8a/MFSaF TSS-7)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1622	Ulixacaltamide NCTID: NCT06087276 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: T-type calcium channels blocker Area: Nervous System Diseases Indication: Essential Tremor	Date: 15 May 2024 Quarter: Q3'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 28 Feb 2025 Lead Time: 289 days in advance Interpretation: ulixacaltamide discontinued further development due to insufficient efficacy at pre-define interim analysis	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: — Sponsor: Praxis Precision Medicines (PRAX)			
1663	AXS07 (meloxicam and rizatriptan) NCTID: NCT05550207 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: COX antagonist and 5HT1B/5HT1D agonist Area: Nervous System Diseases Indication: Migraine Human Patients: 100 Sponsor: Axsome Therapeutics (AXSM)	Date: 6 Aug 2024 Quarter: Q3'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to meloxicam/rizatriptan monotherapy)	Readout: 24 Feb 2025 Lead Time: 202 days in advance Interpretation: AXS07 achieved >24-hour sustained pain relief for 31.2% more patients than after oral CGRPs (p<0.001) and statistically significant mTOQ4 total score superior to oral CGRP inhibitors (p<0.001)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1558	PGN-EDODM1 NCTID: NCT06204809 Phase: Phase 1 Class: First-In-Class Modality: peptide-conjugated antisense oligonucleotide ASO MoA: anti-DMPK-CUG-repeats-specific oligonucleotide Area: Musculoskeletal Diseases Indication: Myotonic Dystrophy Type 1 Human Patients: 32 Sponsor: PepGen (PEPG)	Date: 24 Apr 2024 Quarter: Q3'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in spliceopathy) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit with superior-to-AOC1001 efficacy in terms of vHOT and muscle strength despite non-superior-to-AOC1001 toxicity)	Readout: 24 Feb 2025 Lead Time: 306 days in advance Interpretation: PGN-EDODM1 achieved 29.1% mean splicing correction without improved functional outcomes at day 28 (trends only)	Correct Prediction Conclusion: statistically significant (splicing correction) and commercially maybe sufficient yet weak (functional outcome) Classification: True Negative (TN)
1877	SPN820 (NV-5138) NCTID: NCT05066672 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: mTORC1 activator Area: Mental Disorders Indication: treatment-resistant depression Human Patients: 400 Sponsor: Supernus Pharmaceuticals (SUPN)	Date: 19 Jan 2025 Quarter: Q2'25 Batch 4 Technical: FAILURE (statistically insignificant clinical benefit in MADRS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in MADRS inferior to lumateperone)	Readout: 18 Feb 2025 Lead Time: 30 days in advance Interpretation: SPN820 failed to achieve statistical significance in MADRS total score	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
511	casdatifan (AB521) NCTID: NCT05536141 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: HIF2alpha inhibitor Area: Neoplasms Indication: 3L treatment for metastatic clear cell renal cell carcinoma (ccRCC) Human Patients: 302 Sponsor: Arcus Biosciences (RCUS)	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS compared with placebo) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS non-inferior to cabozantinib as a monotherapy and superior to cabozantinib as a combotherapy)	Readout: 15 Feb 2025 Lead Time: 1 days in advance Interpretation: casdatifan 100mg QD achieved 33% ORR and >6.8 months mPFS; superior to belzutifan that achieved 22% ORR and 5.6 months mPFS; as 3L treatment for ccRCC (10.1056/NEJMoa2313906) and non-inferior to cabozantinib that achieved 21% ORR and 7.4m mPFS as 3L treatment for ccRCC (see the add'l link below)	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
1803	CRB701 NCTID: NCT06265727 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: ADC MoA: anti-nectin4 Area: Neoplasms Indication: 2L treatment for	Date: 19 Oct 2024 Quarter: Q1'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS in 2L/3L clinical setting non-inferior-non-superior to enfortumab vedotin for nectin4-overexpressing advance solid	Readout: 14 Feb 2025 Lead Time: 118 days in advance Interpretation: CRB701 monotherapy achieved 44% ORR as 2L treatment for mUC patients previously treated with enfortumab vedotin (EV); comparable to EV monotherapy that achieve 37.5%-46.8% ORR as 2L	Correct Prediction Conclusion: statistically significant (in ORR non-superior non-inferior to EV) and commercially TBD (wait for OS data) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	nectin4-overexpressing advanced solid tumors Human Patients: 420 Sponsor: Corbus Pharmaceuticals (CRBP)	tumors) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in OS non-inferior-non-superior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors that don't have FDA-approved drugs)	treatment for mUC patients previously treated with chemo + anti-PD1 therapies (see add'l link below and DOI-10.1007/s00432-024-05717-2)	
1841	ALTO-300 NCTID: NCT05922878 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MT1/MT2 agonist and 5HT2C antagonist Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 200 Sponsor: Alto Neuroscience (ANRO)	Date: 9 Nov 2024 Quarter: Q1'25 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet weak (additive) clinical benefit in MADRS) Commercial: FAILURE (commercially insufficient additive clinical benefit in MADRS inferior to lumateperone)	Readout: 12 Feb 2025 Lead Time: 95 days in advance Interpretation: ALTO-300 passed futility test yet failed to achieve sufficient efficacy at interim analysis; an increase of 50 biomarker positive patients are needed in the final analysis whose topline results are expected in mid-2026	Correct Prediction Conclusion: statistically maybe significant (yet weak efficacy) and commercially maybe insufficient Classification: True Negative (TN)
1388	Rosnilimab NCTID: NCT06041269 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: PD1 mAb agonist Area: Immune System Diseases Indication: Rheumatoid Arthritis Human Patients: 420 Sponsor: AnaptysBio (ANAB)	Date: 14 Nov 2024 Quarter: Q1'25 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Feb 2025 Lead Time: 90 days in advance Interpretation: rosnilimab failed to achieve statistical significance in placebo-adjusted ACR50/ACR70 at week 12; inferior to upadacitinib that achieved 28% placebo-adjusted ACR50 and 21% placebo-adjusted ACR70 at week 12 (see add'l link below)	Correct Prediction Conclusion: statistically insignificant (ACR50 at week 12 as the prespecified efficacy endpoint) and commercially insufficient Classification: True Negative (TN)
1861	AZD0171 NCTID: NCT04999969 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-LIF inhibitor Area: Neoplasms Indication: 1L treatment for advanced pancreatic ductal adenocarcinoma (PDAC) Human Patients: 126 Sponsor: AstraZeneca (AZN)	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS compared with chemotherapy alone) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to chemotherapy alone)	Readout: 6 Feb 2025 Lead Time: 61 days in advance Interpretation: AZD0171 + durvalumab + chemotherapy hasn't met the efficacy threshold and further development discontinued without disclosure of data	Missed Prediction Note: due to suboptimal drug MoA model that has been permanently corrected Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1087	Ziftomenib NCTID: NCT05735184 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: MENIN-MLL1 inhibitor Area: Neoplasms Indication: R/R NPM1-m Acute Myeloid Leukemia Human Patients: 212 Sponsor: Kura Oncology (KURA)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in CR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 5 Feb 2025 Lead Time: 102 days in advance Interpretation: ziftomenib achieved statistically significant CR/CRh without disclosing the actual CR/CRh data (which usually indicates unremarkable results); probably inferior to venetoclax + azacitidine's 24-38% CR/CRh (see the add'l link below) combotherapy TBD	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (as monotherapy) Classification: True Negative (TN)
1683	Monlunabant (INV202) NCTID: NCT05514548 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: peripherally selective beta-arrestin-2-biased CB1 inverse agonist	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial FAILURE (statistically insignificant additive clinical benefit in UACR) partial SUCCESS (statistically significant yet moderate additive clinical benefit in UPCR) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 5 Feb 2025 Lead Time: 203 days in advance Interpretation: monlunabant failed to achieve statistical significance in uACR compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient; correct prediction Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Urogenital Diseases Indication: Diabetic Kidney Disease Human Patients: 265 Sponsor: Novo Nordisk (NVO)	Commercial: FAILURE (commercially insufficient additive clinical benefit in eGFR)		
1680	ordesekimab (AMG714/PRV015) NCTID: NCT04424927 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL15 inhibitor Area: Nutritional and Metabolic Diseases Indication: Non-responsive Celiac Disease Human Patients: 226 Sponsor: Amgen / Sanofi (AMGN / SNY)	Date: 14 Jul 2024 Quarter: Q3'24 Batch 17 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in CeD PRO) Commercial: FAILURE (commercially insufficient clinical benefit in CeD PRO)	Readout: 4 Feb 2025 Lead Time: 205 days in advance Interpretation: ordesekimab failed to achieved statistical significance for primary or secondary endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1777	Cemiplimab NCTID: NCT05208944 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: telomere-targeting agent THIO Area: Neoplasms Indication: 3L advanced NSCLC Human Patients: 182 Sponsor: Maia Biotechnology (MAIA)	Date: 2 Sep 2024 Quarter: Q4'24 Batch 15 Technical: partial SUCCESS (statistically significant moderate additive clinical benefit in ORR/PFS as 3L+ treatment) partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in ORR/PFS as 2L treatment) Commercial: partial SUCCESS (commercially sufficient yet moderate additive clinical benefit in OS in combination with cemiplimab superior to chemotherapy + cemiplimab as 3L+ treatment) partial FAILURE (commercially insufficient additive clinical benefit in OS in combination with cemiplimab non-superior to chemotherapy + cemiplimab as 2L treatment)	Readout: 4 Feb 2025 Lead Time: 155 days in advance Interpretation: THIO + cemiplimab achieved 16.9 months mOS (12.5 months mOS as the 95% CI lower bound); superior to the SoC chemotherapy that achieved 10.1 months mOS (see the add'l link below). wait for 2L data.	Correct Prediction Conclusion: statistically significant and commercially sufficient (3L) Classification: True Positive (TP)
1265	GH001 NCTID: NCT05800860 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: psychedelic 5-MeO-DMT Area: Mental Disorders Indication: treatment-resistant depression Human Patients: 80 Sponsor: GH Research (GHR)	Date: 5 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit)	Readout: 3 Feb 2025 Lead Time: 243 days in advance Interpretation: GH001 achieved statistically significant placebo-adjusted -15.5 points MADRS reduction at Day 8 (p<0.0001); superior to esketamine that achieved placebo-adjusted -9 points MADRS reduction at Day 8 (DOI-10.1001/jamapsychiatry.2017.3739)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1631	iscalimab (CFZ533) NCTID: NCT0390552 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD40 inhibitor Area: Immune System Diseases Indication: Sjogren's Syndrome Human Patients: 273 Sponsor: Novartis (NVS)	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: FAILURE (statistically insignificant clinical benefit in ESSDAI or ESSPRI) Commercial: FAILURE (commercially insufficient clinical benefit in ESSDAI or ESSPRI inferior to efgartigimod that's further inferior to rituximab)	Readout: 31 Jan 2025 Lead Time: 214 days in advance Interpretation: iscalimab in cohort 1 failed to achieve statistical significance in dose-response relationship for ESSDAI in 3/4 models; iscalimab 600mg in cohort 2 failed to achieve statistical significance in ESSPRI improvement compared with placebo (p=0.12). Hence; iscalimab hasn't met the efficacy threshold and further development discontinued	Correct Prediction Conclusion: statistically partially insignificant (cohort 1) and commercially insufficient (cohort 2) Classification: True Negative (TN)
1632	LNA043 NCTID: NCT04864392	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14	Readout: 31 Jan 2025 Lead Time: 214 days in advance	Correct Prediction Conclusion: statistically probably

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: ANGPTL3 agonist Area: Immune System Diseases Indication: Knee Osteoarthritis Human Patients: 583 Sponsor: Novartis (NVS)	Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in medial knee cartilage thickness at week 104) Commercial: FAILURE (commercially insufficient clinical benefit inferior to semaglutide in WOMAC pain or 6MWD at week 104)	Interpretation: LNA043 hasn't met the efficacy threshold and further development discontinued without disclosure of data	insignificant and commercially insufficient Classification: True Negative (TN)
1633	LNA043 NCTID: NCT04814368 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: ANGPTL3 agonist Area: Immune System Diseases Indication: Knee Osteoarthritis Human Patients: 23 Sponsor: Novartis (NVS)	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in cartilage volume or KOOS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 31 Jan 2025 Lead Time: 214 days in advance Interpretation: LNA043 + canakinumab hasn't met the efficacy threshold and further development discontinued without disclosure of data	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1636	Secukinumab NCTID: NCT05722522 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL17A inhibitor Area: Nervous System Diseases Indication: Rotator Cuff Tendinopathy Human Patients: 33 Sponsor: Novartis (NVS)	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: FAILURE (statistically insignificant additive clinical benefit in WORC-PSD as an adjunctive therapy to SoC) Commercial: FAILURE (commercially insufficient additive clinical benefit in WORC-PSD as an adjunctive therapy to SoC)	Readout: 31 Jan 2025 Lead Time: 214 days in advance Interpretation: secukinumab hasn't met the efficacy threshold and further development discontinued without disclosure of data	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1657	XXB750 NCTID: NCT05562934 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: long-acting NPR1 agonist Area: Cardiovascular Diseases Indication: Resistant Hypertension Human Patients: 191 Sponsor: Novartis (NVS)	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in mean 24hr SBP at week 12 with moderate toxicity) Commercial: FAILURE (commercially insufficient additive clinical benefit in mean 24hr SBP at week 12 inferior to baxdrostat)	Readout: 31 Jan 2025 Lead Time: 214 days in advance Interpretation: XXB750 hasn't met the efficacy threshold and further development discontinued without disclosure of data	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1081	ZN-c3 (azenosertib) NCTID: NCT05743036 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: BRAF V600E mutant colorectal cancer Human Patients: 44 Sponsor: Zentaris Pharmaceuticals (ZNTL)	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	Readout: 29 Jan 2025 Lead Time: 218 days in advance Interpretation: azenosertib + encorafenib + cetuximab achieved 35-41% confirmed ORR as 1L treatment yet 0% confirmed ORR as 2L treatment. Hence, azenosertib + encorafenib + cetuximab hasn't met the efficacy threshold and further development discontinued	Correct Prediction Conclusion: statistically probably insignificant (combinotherapy for patients not stratified by CCNE1 expression) yet weak additive efficacy and commercially insufficient (combinotherapy discontinued) Classification: True Negative (TN)
1076	ZN-c3 (azenosertib) NCTID: NCT05198804 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: 2L advanced ovarian cancer Human Patients: 117	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: overall FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1)	Readout: 29 Jan 2025 Lead Time: 218 days in advance Interpretation: azenosertib monotherapy 400mg QD5/2 achieved a 31.3% confirmed ORR (5/16) in CCNE1+ patients; azenosertib + niraparib hasn't met the efficacy threshold and further development discontinued	Correct Prediction Conclusion: statistically partially significant (monotherapy for CCNE1+ patients only) yet weak additive efficacy and commercially insufficient (combinotherapy discontinued) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Zentaris Pharmaceuticals (ZNTL)	expression)		
526	Sirexatamab (DKN-01) NCTID: NCT05480306 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-DKK1 inhibitor Area: Neoplasms Indication: 2L MSS Colorectal Cancer Human Patients: 189 Sponsor: Leap Therapeutics (LPTX)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 Lead Time: 275 days in advance Interpretation: sirexatamab + bevacizumab + chemotherapy achieved a 12% delta in confirmed ORR (35% vs 23%); compared with bevacizumab + chemotherapy	Correct Prediction Conclusion: statistically maybe significant yet weak additive efficacy and commercially probably insufficient (weak additive ORR) Classification: True Negative (TN)
525	Sirexatamab (DKN-01) NCTID: NCT04363801 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-DKK1 inhibitor Area: Neoplasms Indication: Gastric or Gastroesophageal Cancer Human Patients: 232 Sponsor: Leap Therapeutics (LPTX)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 Lead Time: 275 days in advance Interpretation: sirexatamab + tislelizumab + chemotherapy achieved a 3% delta in confirmed ORR (52% vs 49% in average) and -2.5 months delta in PFS (8.69 months in average vs 11.2 months in average) compared with tislelizumab + chemotherapy (though the median PFS for tislelizumab plus chemotherapy in the Phase 3 Rationale-305 study was 6.9 months (95% CI- 5.7; 7.2); further developments discontinued due to weak efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1717	Enobosarm NCTID: NCT06282458 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: nonsteroidal selective androgen receptor modulator Area: Nutritional and Metabolic Diseases Indication: Muscle Loss Obesity Human Patients: 150 Sponsor: Veru (VERU)	Date: 13 Oct 2024 Quarter: Q1'25 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in lowering the reduction of total lean body mass with the toxicity of weakening muscle strength) Commercial: FAILURE (commercially insufficient additive clinical benefit with inferior-to-semaglutide reduction in total fat mass)	Readout: 27 Jan 2025 Lead Time: 106 days in advance Interpretation: Enobosarm achieved a placebo-adjusted 2.9% reduction of muscle loss (p=0.002) superior to semaglutide; yet a placebo-adjusted 2.3% improvement of fat loss (p=0.096) non-superior to semaglutide; and a placebo-adjusted 0.3kg less weight loss slightly inferior to semaglutide	Correct Prediction Conclusion: statistically significant and commercially maybe insufficient (weak efficacy) Classification: True Negative (TN)
1813	AK006 NCTID: NCT06072157 Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody MoA: anti-SIGLEC6 inhibitor Area: Immune System Diseases Indication: Chronic Spontaneous Urticaria Human Patients: 136 Sponsor: Allakos (ALLK)	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4 Technical: FAILURE (statistically insignificant clinical benefit in UAS7/ISS7 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in UAS7/ISS7 inferior to barzolvolimab)	Readout: 27 Jan 2025 Lead Time: 85 days in advance Interpretation: AK006 failed to demonstrate therapeutic efficacy and further developments discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1851	Semaglutide NCTID: NCT05646706 Phase: Phase 3 Class: Best-In-Class Modality: peptide MoA: GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 1407	Date: 3 Dec 2024 Quarter: Q1'25 Batch 12 Technical: SUCCESS (statistically significant clinical benefit in overall/stratified weight reduction against placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in overall/stratified weight reduction superior to semaglutide)	Readout: 17 Jan 2025 Lead Time: 45 days in advance Interpretation: semaglutide 7.2mg achieved 18.3% placebo-adjusted weight reduction at week 72; thus superior to 15.1% placebo-adjusted weight reduction at week 72 achieved by semaglutide 2.4mg (higher than 12.5% placebo-adjusted weight reduction at week 68 achieved by semaglutide 2.4mg in the pivotal trial)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Novo Nordisk (NVO)	2.4mg; superior to tirzepatide; yet inferior to VK2735)	DOI-10.1056/NEJMoa2032183); inferior to 20.1% placebo-adjusted weight reduction at week 72 achieved by tirzepatide	
921	Emiltatug Ledadotin (XMT-1660) NCTID: NCT05377996 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: DAR-6 anti-B7-H4 ADC with an AF-HPA payload Area: Neoplasms Indication: Triple Negative Breast Cancer Breast Cancer Endometrial Cancer Ovarian Cancer Fallopian Tube Cancer Primary Peritoneal Cavity Cancer Adenoid Cystic Carcinoma Human Patients: 319 Sponsor: Mersana Therapeutics (MRSN)	Date: 14 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with high toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 10 Jan 2025 Lead Time: 271 days in advance Interpretation: XMT1660 achieved 19% confirmed ORR for all B7-H4 high patients across all doses (11/57)	Correct Prediction Conclusion: statistically maybe significant yet weak clinical efficacy (low ORR) and commercially probably insufficient Classification: True Negative (TN)
1264	GH001 NCTID: NCT05804708 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: psychedelic 5-MeO-DMT Area: Mental Disorders Indication: Postpartum Depression Human Patients: 10 Sponsor: GH Research (GHR)	Date: 5 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit)	Readout: 10 Jan 2025 Lead Time: 219 days in advance Interpretation: GH001 achieved statistically significant of -35.4 points MADRS reduction at Day 8 (p<0.0001; placebo data not disclosed)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (pending placebo data disclosure to evaluate efficacy competitiveness) Classification: True Positive (TP)
1263	GH001 NCTID: NCT05839509 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: psychedelic 5-MeO-DMT Area: Mental Disorders Indication: Bipolar II Disorder Human Patients: 6 Sponsor: GH Research (GHR)	Date: 5 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit)	Readout: 10 Jan 2025 Lead Time: 219 days in advance Interpretation: GH001 achieved statistically significant -16.8 points MADRS reduction at Day 8 (p=0.0099; superior to -8 points MADRS reduction at Day 8 achieved by quetiapine; though absolute MADRS reduction values are not directly comparable due to varying placebo effects especially for psychiatric disorders)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (pending placebo data disclosure to evaluate efficacy competitiveness) Classification: True Positive (TP)
1808	Imvotamab NCTID: NCT06524687 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-CD3 anti-CD20 T-cell engager Area: Musculoskeletal Diseases Indication: Idiopathic Inflammatory Myopathies Human Patients: 2 Sponsor: IGM Biosciences (IGMS)	Date: 26 Oct 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in MMT8 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in MMT8)	Readout: 9 Jan 2025 Lead Time: 75 days in advance Interpretation: Imvotamab failed to demonstrate sufficient efficacy and further development discontinued accordingly	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1807	Imvotamab NCTID: NCT06041568 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-CD3 anti-CD20 T-cell engager	Date: 26 Oct 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in BICLA/SRI4 against placebo)	Readout: 9 Jan 2025 Lead Time: 75 days in advance Interpretation: Imvotamab failed to demonstrate sufficient efficacy and further development discontinued accordingly	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Immune System Diseases Indication: Severe Systemic Lupus Erythematosus Human Patients: 17 Sponsor: IGM Biosciences (IGMS)	Commercial: FAILURE (commercially insufficient clinical benefit in BICLA/SRI4)		
1806	Imvotamab NCTID: NCT06087406 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-CD3 anti-CD20 T-cell engager Area: Immune System Diseases Indication: Moderate to Severe Rheumatoid Arthritis Human Patients: 33 Sponsor: IGM Biosciences (IGMS)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in DAS28-CRP or ACR20 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in DAS28-CRP or ACR20)	Readout: 9 Jan 2025 Lead Time: 75 days in advance Interpretation: Imvotamab failed to demonstrate sufficient efficacy and further development discontinued accordingly	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1711	Briquilimab NCTID: NCT06162728 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-ckIT mAb inhibitor Area: Immune System Diseases Indication: Chronic Spontaneous Urticaria Human Patients: 80 Sponsor: Jasper Therapeutics (JSPR)	Date: 31 Jul 2024 Quarter: Q3'24 Batch 21 Technical: SUCCESS (statistically significant clinical benefit in UAS7) Commercial: FAILURE (commercially insufficient clinical benefit in UAS7 inferior to barzolvolimab)	Readout: 8 Jan 2025 Lead Time: 161 days in advance Interpretation: briquilimab highest dose 180mg Q8W achieved 21% placebo-adjusted CR at week 12 vs. 31% placebo-adjusted CR at week 12 achieved by barzolvolimab highest dose in NCT05368285 vs 27% placebo-adjusted CR at week 12 achieved by omalizumab in ASTERIA I study (DOI-0.1038/jid.2014.306)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to both omalizumab and barzolvolimab) Classification: True Negative (TN)
1449	daxdilimab NCTID: NCT05368103 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-ILT7 inhibitor Area: Skin and Connective Tissue Diseases Indication: Alopecia Areata Human Patients: 30 Sponsor: Amgen (AMGN)	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 7 Jan 2025 Lead Time: 337 days in advance Interpretation: daxdilimab achieved 13.3% SALT20 response at week 24; which would be inferior to ritilecitinib that achieved 29.1% placebo-adjusted SALT20 response at week 24 (see the add'l link below); Further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant (no placebo arm) and commercially insufficient Classification: True Negative (TN)
1487	DNL343 NCTID: NCT05842941 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: transferrin-receptor-mediated BBB-crossing EIF2beta activator Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis Human Patients: 249 Sponsor: Denali Therapeutics / AbbVie (DNL1 / ABBV)	Date: 27 Feb 2024 Quarter: Q4'24 Batch 2 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 6 Jan 2025 Lead Time: 314 days in advance Interpretation: DNL343 failed to achieve its primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1576	Navacaprant (NMRA-335140) NCTID: NCT06029426 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: KOR antagonist Area: Mental Disorders	Date: 14 Aug 2024 Quarter: Q4'24 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 2 Jan 2025 Lead Time: 141 days in advance Interpretation: navacaprant failed to meet the primary efficacy endpoint MADRS total score compared to placebo; non-superior to aticaprant that achieved borderline statistical	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

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#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Major Depressive Disorder Human Patients: 332 Sponsor: Neumora Therapeutics (NMRA)	insufficient clinical benefit non-superior non-inferior to aticaprant; yet inferior to lumateperone)	significance in MADRS total score in phase 2 trial (p=0.044)	
898	AXS-05 NCTID: NCT05557409 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: NMDAR antagonist & sigma-1 receptor agonist Area: Nervous System Diseases Indication: Alzheimer's Disease Agitation Human Patients: 350 Sponsor: Axsome Therapeutics (AXSM)	Date: 6 Jul 2024 Quarter: Q3'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in CMAI) Commercial: SUCCESS (commercially sufficient clinical benefit in CMAI definitely non-inferior to and maybe superior to brexpiprazole)	Readout: 30 Dec 2024 Lead Time: 177 days in advance Interpretation: AXS05 failed to meet any primary and secondary efficacy endpoints	Missed Prediction Note: due to suboptimal drug MoA modelling that has been permanently improved Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1514	CagriSema NCTID: NCT06131437 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: combo amylin analog + GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 800 Sponsor: Novo Nordisk (NVO)	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in weight reduction superior to tirzepatide yet non-superior to VK2735 for nondiabetic obese young population) Commercial: SUCCESS (commercially sufficient clinical benefit in total lean body mass preservation and total fat body mass reduction/change in waist circumference superior to tirzepatide yet non-superior to VK2735 for nondiabetic obese young population)	Readout: 20 Dec 2024 Lead Time: 121 days in advance Interpretation: CagriSema achieved 20.4% placebo-adjusted weight loss at week 68; which is superior to semaglutide that achieved 13.8% placebo-adjusted weight loss at week 68 and cagrilintide that achieved 9.5% placebo-adjusted weight loss at week 68 as the active control arm; tirzepatide achieved 19.5% placebo-adjusted weight loss at week 68 (DOI- 10.1056/NEJMoa2206038); VK2735 achieved 13.1% placebo-adjusted weight loss at week 13 (see add'l link below); superior to tirzepatide's 7% placebo-adjusted weight loss at week 13 and probably superior to CagriSema's undisclosed (yet estimated to be 8-10%) placebo-adjusted weight loss at week 13	Correct Prediction Conclusion: statistically significant and commercially sufficient (numerically superior to tirzaptide yet probably non-superior to VK2735) Classification: True Positive (TP)
1517	CagriSema NCTID: NCT05567796 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: combo amylin analog + GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 3400 Sponsor: Novo Nordisk (NVO)	Date: 24 Mar 2024 Quarter: Q3'24 Batch 18 Technical: SUCCESS (statistically significant clinical benefit in weight reduction) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-semaglutide-and-cagrilintide efficacy weight reduction)	Readout: 20 Dec 2024 Lead Time: 271 days in advance Interpretation: CagriSema achieved 20.4% placebo-adjusted weight loss at week 68; which is superior to semaglutide that achieved 13.8% placebo-adjusted weight loss at week 68 and cagrilintide that achieved 9.5% placebo-adjusted weight loss at week 68 as the active control arm; tirzepatide achieved 19.5% placebo-adjusted weight loss at week 68 (DOI- 10.1056/NEJMoa2206038); VK2735 achieved 13.1% placebo-adjusted weight loss at week 13 (see add'l link below); superior to tirzepatide's 7% placebo-adjusted weight loss at week 13 and probably superior to CagriSema's undisclosed (yet estimated to be 8-10%) placebo-adjusted weight loss at week 13	Correct Prediction Conclusion: statistically significant and commercially sufficient (numerically superior to tirzaptide yet probably non-superior to VK2735) Classification: True Positive (TP)
1744	Belapectin NCTID: NCT04365868 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: galectin-3 inhibitor Area: Nutritional and Metabolic	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in esophageal varices prevention)	Readout: 20 Dec 2024 Lead Time: 132 days in advance Interpretation: belapectin failed to achieve statistical significance in the primary endpoint of esophageal varices compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Diseases Indication: Cirrhotic Portal Hypertension Caused by Metabolic Dysfunction-Associated Steatohepatitis (MASH) Human Patients: 357 Sponsor: Galectin Therapeutics (GALT)	Commercial: FAILURE (commercially insufficient clinical benefit in esophageal varices prevention inferior to beta blockers)		
1390	Dostarlimab (TSR-042) NCTID: NCT03602859 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-PD1 mAb inhibitor Area: Neoplasms Indication: 1L combotherapy treatment for advanced ovarian cancer Human Patients: 1402 Sponsor: GSK (GSK)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS) Commercial: FAILURE (commercially maybe sufficient yet very weak additive clinical benefit in OS)	Readout: 20 Dec 2024 Lead Time: 127 days in advance Interpretation: dostarlimab + SoC + niraparib +/- bevacizumab achieved statistical significance in PFS yet failed to achieve statistical significance in OS; compared with SoC + niraparib +/- bevacizumab	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (OS) Classification: True Negative (TN)
1485	PYX106 NCTID: NCT05718557 Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody MoA: anti-SIGLEC-15 inhibitor Area: Neoplasms Indication: dvanced solid tumors Human Patients: 60 Sponsor: Pyxis Oncology (PYXS)	Date: 9 Apr 2024 Quarter: Q3'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PFS/OS/ORR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 19 Dec 2024 Lead Time: 254 days in advance Interpretation: PYX106 is safe yet probably ineffective (no ORR data disclosed for 45 patients) and its further development discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1694	REGN9933 NCTID: NCT05618808 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-Factor-XI inhibitor Area: Cardiovascular Diseases Indication: Venous thromboembolism (VTE) Human Patients: 373 Sponsor: Regeneron Pharmaceuticals (REGN)	Date: 22 Jul 2024 Quarter: Q3'24 Batch 19 Technical: partial SUCCESS (statistically significant clinical benefit in reduction of major bleeding incidence superior to enoxaparin/apixaban) partial FAILURE (statistically maybe insignificant clinical benefit in non-bleeding TEAE maybe inferior to enoxaparin/apixaban) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in reduction of venous thromboembolism incidence non-superior to enoxaparin/apixaban)	Readout: 19 Dec 2024 Lead Time: 150 days in advance Interpretation: REGN9933 achieved 17% VTE event rate; superior to enoxaparin's 21% VTE event rate yet inferior to apixaban's 12% VTE event rate; REGN9933 achieved 22% AE rate; inferior to enoxaparin's 21% AE rate yet superior to apixaban's 25% AE rate	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to enoxaparin/apixaban in a crowded market) Classification: True Negative (TN)
1854	Suzetrigine (VX-548) NCTID: NCT06176196 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral Nav1.8/SCN10A inhibitor Area: Nervous System Diseases Indication: Painful Lumbosacral Radiculopathy Human Patients: 218 Sponsor: Vertex Pharmaceuticals (VRTX)	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in NPRS at week 12 against placebo) partial FAILURE (statistically insignificant clinical benefit in DSIS at week 12 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in NPRS/DSIS/TEAE non-superior to NSAIDs and inferior to epidural steroid injection)	Readout: 19 Dec 2024 Lead Time: 12 days in advance Interpretation: suzetrigine achieved non-superior-non-inferior-to-placebo efficacy in NPRS at week 12 (-2.02 vs -1.98 without disclosing p-value); DSIS data not disclosed	Correct Prediction Conclusion: statistically insignificant (NPRS) and commercially insufficient Classification: True Negative (TN)
1368	Prasinezumab NCTID: NCT04777331	Date: 30 Nov 2023 Quarter: Q3'24 Batch 17	Readout: 19 Dec 2024 Lead Time: 385 days in advance	Correct Prediction Conclusion: statistically

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-alpha-synuclein Area: Nervous System Diseases Indication: Early Parkinson's Disease Human Patients: 586 Sponsor: Prothena / Roche (PRTA/ RHHBY)	Technical: FAILURE (commercially insufficient clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Interpretation: prasinezumab failed to meet any primary and secondary efficacy endpoints	insignificant and commercially insufficient Classification: True Negative (TN)
1708	KB707 NCTID: NCT06228326 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: intratumorally injected HSV1-delivered IL2 and IL12 Area: Neoplasms Indication: advanced non-small cell lung cancer (NSCLC) Human Patients: 140 Sponsor: Krystal Biotech (KRYS)	Date: 31 Jul 2024 Quarter: Q3'24 Batch 21 Technical: partial SUCCESS (statistically maybe significant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 18 Dec 2024 Lead Time: 140 days in advance Interpretation: KB707 achieved 27% confirmed ORR (6/33) for any advanced NSCLC patients; non-superior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR for EGFRwt advanced NSCLC patients (10.1016/j.lungcan.2018.12.015) and inferior to osimertinib that achieved 71% ORR for EGFRmut advanced NSCLC patients (10.1056/NEJMoa1612674); OS data pending	Correct Prediction Conclusion: statistically significant yet weak (in ORR) and commercially probably insufficient (in ORR with OS data pending) Classification: True Negative (TN)
1619	CT1812 NCTID: NCT05225415 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: allosteric sigma-2 receptor antagonist Area: Nervous System Diseases Indication: Dementia With Lewy Bodies Human Patients: 130 Sponsor: Cognition Therapeutics (CGTX)	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit despite tolerable toxicity) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 18 Dec 2024 Lead Time: 217 days in advance Interpretation: CT1812 met the safety primary endpoint with trends only of cognitive/functional improvements	Correct Prediction Conclusion: statistically significant (safety) and commercially probably insufficient (efficacy) Classification: True Negative (TN)
1701	duvakitug (TEV'574/SAR447189) NCTID: NCT05499130 Phase: Phase 2 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-TL1A mAb inhibitor Area: Immune System Diseases Indication: Severe Ulcerative Colitis and Crohn's Disease Human Patients: 290 Sponsor: Teva Pharmaceuticals / Sanofi (TEVA / SNY)	Date: 27 Jul 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in clinical remission and endoscopic response against placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in clinical remission and endoscopic response non-superior and non-inferior to PRA023)	Readout: 17 Dec 2024 Lead Time: 143 days in advance Interpretation: duvakitug (high-dose) achieved 27.4% placebo-adjusted clinical remission rate at week 14 (p=0.003) for UC patients; numerically superior to PRA023 that achieved 25% placebo-adjusted clinical remission rate at week 12 for UC patients; duvakitug (high-dose) achieved 34.8% placebo-adjusted clinical remission rate at week 14 (p<0.001) for CD patients; numerically superior to PRA023 that achieved 33.1% placebo-adjusted clinical remission rate at week 12 for CD patients (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
428	AFM24 NCTID: NCT05109442 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: EGFR x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Selected Advanced/Metastatic EGFR-expressing Cancers Human Patients: 148 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 17 Dec 2024 Lead Time: 292 days in advance Interpretation: FM24 + atezolizumab achieved 18% confirmed ORR (6/33) for EGFRwt advanced NSCLC patients; numerically inferior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR (10.1016/j.lungcan.2018.12.015); AFM24 + atezolizumab achieved 24% confirmed ORR (4/17) for EGFRmut advanced NSCLC patients; inferior to osimertinib that achieved 71% ORR	Correct Prediction Conclusion: statistically significant yet weak (in ORR) and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view: **Oncology** Immunology Metabolic Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
			(10.1056/NEJMoa1612674)	
1129	Lonaepsomatropin NCTID: NCT05690386 Phase: Phase 2 Class: Best-In-Class Modality: peptide MoA: long-lasting growth hormone Area: Urogenital Diseases Indication: Turner Syndrome Human Patients: 48 Sponsor: Ascendis Pharma (ASND)	Date: 29 Aug 2024 Quarter: Q4'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to daily somatropin)	Readout: 16 Dec 2024 Lead Time: 109 days in advance Interpretation: lonaepsomatropin met the primary endpoint of annualized height velocity at week 26; similar to daily somatropin	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)
1567	minzasolmin (UCB0599) NCTID: NCT04658186 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: ASYN-misfolding inhibitor Area: Nervous System Diseases Indication: Early-stage Parkinson's Disease Human Patients: 496 Sponsor: UCB Biopharma (UCB)	Date: 26 Apr 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in MDS-UPDRS) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-levodopa efficacy in MDS-UPDRS)	Readout: 16 Dec 2024 Lead Time: 234 days in advance Interpretation: minzasolmin failed to meet any primary and secondary efficacy endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1719	LYT100 NCTID: NCT05321420 Phase: Phase 2 Class: Best-In-Class Modality: deuterated formulation MoA: a deuterated form of pirfenidone Area: Respiratory Tract Diseases Indication: Idiopathic Pulmonary Fibrosis Human Patients: 240 Sponsor: PureTech (PRTC)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 3 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in FVC against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in FVC inferior to pirfenidone)	Readout: 16 Dec 2024 Lead Time: 132 days in advance Interpretation: LYT100 550mg TID (equivalent to the approved pirfenidone 801 mg TID) achieved a 1.62% placebo-adjusted improvement in FVCpp; at least numerically inferior to the SoC (pirfenidone 801mg TID) that achieved a 1.97% placebo-adjusted improvement in FVCpp	Correct Prediction Conclusion: statistically significant yet weak (in FVCpp) and commercially insufficient (inferior to pirfenidone); Classification: True Negative (TN)
1251	Sevasemten (EDG-5506) NCTID: NCT05291091 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral selective fast skeletal muscle myosin inhibitor Area: Musculoskeletal Diseases Indication: Becker Muscular Dystrophy Human Patients: 170 Sponsor: Edgewise Therapeutics (EWTX)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in TNNI2) Commercial: FAILURE (commercially insufficient clinical benefit in either NSAA or 6MWD)	Readout: 16 Dec 2024 Lead Time: 132 days in advance Interpretation: sevasemten achieved 77% reduction in plasma TNNI2 (p<0.001); sevasemten failed to achieved statistically significant improvement in NSAA (p=0.16).	Correct Prediction Conclusion: statistically significant (TNNI2) and commercially insufficient (NSAA) Classification: True Negative (TN)
1409	CTI-1601 NCTID: NCT05579691 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: TAT-delivered FXN recombinant fusion protein Area: Nervous System Diseases Indication: Friedreich Ataxia Human Patients: 28 Sponsor: Larimar Therapeutics (LRMR)	Date: 7 Jan 2024 Quarter: Q1'24 Batch 14 Technical: partial SUCCESS (statistically significant yet weak clinical benefit due to TAT delivery) Commercial: FAILURE (commercially insufficient clinical benefit inferior to omaveloxolone)	Readout: 16 Dec 2024 Lead Time: 344 days in advance Interpretation: nomlabofusp achieved early trends yet very weak improvements in mFARS	Correct Prediction Conclusion: statistically maybe significant yet weak (mFARS) and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1421	Palbociclib NCTID: NCT02947685 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: HR+/HER2+ advanced breast cancer Human Patients: 496 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS but not in OS) Commercial: partial SUCCESS (commercially sufficient yet limited additive clinical benefit in PFS but not in OS)	Readout: 13 Dec 2024 Lead Time: 333 days in advance Interpretation: palbociclib + anti-HER2 therapy + endocrine therapy achieved 44.3 months mPFS; superior to anti-HER2 therapy + endocrine therapy that achieved 29.1 months mPFS (p=0.0074); OS analysis remains immature yet palbociclib's improvement in 5-year survival rate is small (74.3% vs 69.8% HR 0.86; 95% CI)	Correct Prediction Conclusion: statistically significant (in PFS) and commercially TBD (wait for OS data) Classification: True Positive (TP)
1770	BBI-825 NCTID: NCT06299761 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: RNR inhibitor Area: Neoplasms Indication: advanced solid tumours with resistance oncogene amplifications Human Patients: 42 Sponsor: Boundless Bio (BOLD)	Date: 29 Aug 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 12 Dec 2024 Lead Time: 105 days in advance Interpretation: BBI825's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
851	lunresertib (RP-6306) and camonsertib (RP-3500) NCTID: NCT04855656 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: PKMYT1 inhibitor and ATR inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 364 Sponsor: Repare Therapeutics (RPTX)	Date: 18 Jan 2023 Quarter: 1H'23 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Dec 2024 Lead Time: 694 days in advance Interpretation: lunresertib + camonsertib achieved 18.5% confirmed ORR (5/27) for endometrial cancer; which is non-superior to pembrolizumab + lenvatinib that achieved 38% ORR (DOI-10.6004/jadpro.2022.13.1.4); lunresertib + camonsertib achieved 16.7% confirmed ORR (4/24) for platinum-resistant ovarian cancer; which is inferior to chemotherapy + bevacizumab that achieved 27.3% ORR	Correct Prediction Conclusion: statistically maybe significant yet weak (in ORR) and commercially insufficient (in ORR) Classification: True Negative (TN)
1706	Nebulization (KB408) NCTID: NCT06049082 Phase: Phase 1 Class: First-In-Class Modality: inhaled formulation MoA: inhaled replication-defective HSV1-delivered SERPINA1 Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Alpha 1-Antitrypsin Deficiency (AATD) Human Patients: 12 Sponsor: Krystal Biotech (KRYS)	Date: 31 Jul 2024 Quarter: Q3'24 Batch 21 Technical: partial SUCCESS (statistically significant clinical benefit in lung AAT concentration) partial FAILURE (statistically insignificant clinical benefit in lung NE level) Commercial: FAILURE (commercially insufficient clinical benefit in FEV1)	Readout: 12 Dec 2024 Lead Time: 134 days in advance Interpretation: KB408 achieved 5.3-9.7 micromolar mean total AAT protein; inferior to the 10.8 micromolar mean total AAT protein achieved by WVE006	Correct Prediction Conclusion: statistically significant (AAT concentration) and commercially TBD (wait for FEV1 data) Classification: True Positive (TP)
551	Dazucorilant NCTID: NCT05407324 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: lipid selective glucocorticoid receptor antagonist Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis (ALS) Human Patients: 249 Sponsor: Corcept Therapeutics	Date: 14 Apr 2024 Quarter: Q4'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Dec 2024 Lead Time: 241 days in advance Interpretation: dazucorilant failed to achieve its primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	(CORT)			
1387	ANB032 NCTID: NCT05935085 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-BTLA mAb agonist Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis Human Patients: 160 Sponsor: AnaptysBio (ANAB)	Date: 30 Aug 2024 Quarter: Q4'24 Batch 15 Technical: partial SUCCESS (statistically significant yet weak clinical benefit in EASI75) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 non-superior to dupilumab inferior to upadacitinib/NM26)	Readout: 11 Dec 2024 Lead Time: 103 days in advance Interpretation: ANB032 failed to achieve achieved statistical significance in placebo-adjusted EASI75 at week 14	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1686	Imlunestrant NCTID: NCT04975308 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral next-gen SERD Area: Neoplasms Indication: 2L HR+/HER2-Metastatic Breast Cancer Human Patients: 866 Sponsor: Eli Lilly and Company (LLY)	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically significant clinical benefit in PFS/OS non-superior non-inferior to fulvestrant/exemestane) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in combination with abemaciclib as all-oral regimens; despite non-superior efficacy in PFS/OS compared with fulvestrant/exemestane + abemaciclib)	Readout: 11 Dec 2024 Lead Time: 147 days in advance Interpretation: imlunestrant + SoC failed to achieve statistical significance in PFS compared with SoC alone in all patients (5.6 months vs 5.5 months; p=0.12); imlunestrant + abemaciclib achieved statistical significance in PFS compared with imlunestrant alone in all patients (9.4 months vs 5.5 months p<0.001); OS data immature	Correct Prediction Conclusion: partially statistically insignificant (monotherapy in PFS) and partially statistically significant (combination in PFS) and commercially TBD (wait for OS data) Classification: True Positive (TP)
420	CAN2409 NCTID: NCT02768363 Phase: Phase 2 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: newly diagnosed prostate cancer Human Patients: 187 Sponsor: Candel Therapeutics (CADL)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant clinical benefit in PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 11 Dec 2024 Lead Time: 127 days in advance Interpretation: CAN2409 failed achieved statistical significance in DFS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
421	CAN2409 NCTID: NCT01436968 Phase: Phase 3 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: localized prostate cancer Human Patients: 711 Sponsor: Candel Therapeutics (CADL)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant additive clinical benefit in DFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 11 Dec 2024 Lead Time: 127 days in advance Interpretation: CAN2409 + RT achieved statistically significant 14.5% relative improvement in DFS at month 54 (not the prespecified month 60) over RT alone (p=0.0155); CAN2409 + RT probably failed to achieve statistical significance in OS improvement (no mentioning of OS data in the topline readout)	Correct Prediction Conclusion: statistically significant yet weak (borderline for DFS) and commercially insufficient (for OS) Classification: True Negative (TN)
1716	Bempikibart (ADX-914) NCTID: NCT06018428 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL7Ralpha mAb inhibitor Area: Skin and Connective	Date: 14 Aug 2024 Quarter: Q4'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in SALT score against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in SALT	Readout: 10 Dec 2024 Lead Time: 118 days in advance Interpretation: bempikibart probably failed to achieve statistical significance in the primary efficacy endpoint SALT score at week 24 (16% vs 2% placebo with a p=0.045 after excluding three placebo	Correct Prediction Conclusion: statistically probably significant and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Tissue Diseases Indication: Severe Alopecia Areata Human Patients: 40 Sponsor: Q32 Bio (QTTB)	score inferior to baricitinib)	patients)	
1715	Bempikibart (ADX-914) NCTID: NCT05509023 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL7Ralpha mAb inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis Human Patients: 102 Sponsor: Q32 Bio (QTTB)	Date: 14 Aug 2024 Quarter: Q4'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab)	Readout: 10 Dec 2024 Lead Time: 118 days in advance Interpretation: bempikibart failed to achieve statistical significance in the primary efficacy endpoint EASI at week 14	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
913	Tildacerfont NCTID: NCT04544410 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CRF1R antagonist Area: Urogenital Diseases Indication: Adult Congenital Adrenal Hyperplasia (CAH) Human Patients: 90 Sponsor: Spruce Biosciences (SPRB)	Date: 30 Nov 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 10 Dec 2024 Lead Time: 376 days in advance Interpretation: ildacerfont did not achieve statistical significance in GC level reduction	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
912	Tildacerfont NCTID: NCT05128942 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CRF1R antagonist Area: Urogenital Diseases Indication: pediatric Congenital Adrenal Hyperplasia (CAH) Human Patients: 70 Sponsor: Spruce Biosciences (SPRB)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 10 Dec 2024 Lead Time: 376 days in advance Interpretation: tildacerfont did not achieve statistical significance in A4/GC level reduction	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1012	Obicetrapib NCTID: NCT05142722 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective CETP inhibitor Area: Nutritional and Metabolic Diseases Indication: Atherosclerotic Cardiovascular Disease (ASCVD) / Heterozygous familial hypercholesterolemia (HeFH) Human Patients: 2532 Sponsor: NewAmsterdam Pharma (NAMS)	Date: 12 May 2024 Quarter: Q4'24 Batch 10 Technical: FAILURE (statistically insignificant additive clinical benefit of obicetrapib in MACE or cardiovascular hospitalization with significantly increased toxicity-driven mortality) Commercial: FAILURE (commercially insufficient additive clinical benefit of obicetrapib in MACE or cardiovascular hospitalization with significantly increased toxicity-driven mortality)	Readout: 10 Dec 2024 Lead Time: 212 days in advance Interpretation: obicetrapib + SoC did not achieve statistical significance in MACE reduction compared with SoC alone (0.79 HR)	Correct Prediction Conclusion: statistically insignificant (insignificant MACE reduction benefit) and commercially insufficient (insufficient MACE reduction benefit) Classification: True Negative (TN)
522	Palazestrant (OP-125) NCTID: NCT05508906 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: CERAN and SERD Area: Neoplasms	Date: 18 Jun 2023 Quarter: 2H'23 Batch 6 Technical: partial SUCCESS (statistically significant additive clinical benefit for OP-1250 + ribociclib) partial FAILURE (statistically insignificant additive	Readout: 10 Dec 2024 Lead Time: 541 days in advance Interpretation: palazestrant + ribociclib achieved 27% ORR (10/37); superior to both sacituzumab govitecan's 21% ORR and chemotherapy's 14% ORR (see add'l	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: 2L treatment for HR+/HER2- Metastatic Breast Cancer Human Patients: 155 Sponsor: Olema Pharmaceuticals (OLMA)	clinical benefit for OP-1250 + alpelisib) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit for OP-1250 + ribociclib) partial FAILURE (commercially insufficient additive clinical benefit for OP-1250 + alpelisib)	link below); no data disclosed for OP-1250 + alpelisib	
1762	Neflamapimod NCTID: NCT05869669 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: p38alpha inhibitor Area: Nervous System Diseases Indication: Dementia With Lewy Bodies Human Patients: 160 Sponsor: CervoMed (CRVO)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in CDR-SB) Commercial: FAILURE (commercially insufficient additive clinical benefit in MSD-UPDRS3)	Readout: 10 Dec 2024 Lead Time: 113 days in advance Interpretation: neflamapimod failed to meet the primary efficacy endpoint CDR-SB; no data disclosed for MSD-UPDRS3	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1490	AFM28 NCTID: NCT05817058 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: CD123 x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 30 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in ORR/CR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 Dec 2024 Lead Time: 284 days in advance Interpretation: AFM28 achieved 31% CR/CRi (5/16 for 250mg and 300mg); inferior to SoC that achieved 69% CR/CRi (see add'l link below)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: True Negative (TN)
1550	R906289 Monosodium (R289 Na) NCTID: NCT05308264 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: IRAK1/IRAK4 inhibitor Area: Neoplasms Indication: R/R Lower-risk Myelodysplastic Syndromes (LR MDS) that have exhausted all the other treatment options Human Patients: 34 Sponsor: Rigel Pharmaceuticals (RIGL)	Date: 15 Apr 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 9 Dec 2024 Lead Time: 238 days in advance Interpretation: R289 achieved 40% hematologic responses (≥ 50% improvement in hemoglobin (Hb) and 30% RBC-TI mg QD) for 8 week and 1 Grade3 AST/Grade4 ALT TEAE	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
1456	Tavapadon NCTID: NCT04223193 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: a selective D1R/D5R partial agonist Area: Nervous System Diseases Indication: early Parkinson's Disease Human Patients: 304 Sponsor: AbbVie (ABBV)	Date: 14 Feb 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit superior to levodopa for patients who receive tavapadon + MAOB inhibitor combotherapy) partial FAILURE (commercially insufficient clinical benefit non-superior to levodopa for patients who receive tavapadon monotherapy)	Readout: 9 Dec 2024 Lead Time: 299 days in advance Interpretation: tavapadon monotherapy achieved -9.1 improvement (p< 0.0001) in MDS-UPDRS Parts II and III combined score at week 26; non-superior to -10.2 improvement in MDS-UPDRS total score achieved by Levodopa at week 26 (no data announced for tavapadon + MAOA combotherapy)	Correct Prediction Conclusion: statistically significant and commercially insufficient (as monotherapy) Classification: True Negative (TN)
1679	REL-1017 NCTID: NCT06011577 Phase: Phase 3 Class: First-In-Class	Date: 14 Jul 2024 Quarter: Q3'24 Batch 17 Technical: FAILURE (statistically insufficient additive clinical benefit)	Readout: 9 Dec 2024 Lead Time: 148 days in advance Interpretation: REL-1017 will be discontinued for lack of efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule MoA: GLUN1-GLUN2D antagonist Area: Mental Disorders Indication: major depressive disorder (MDD) Human Patients: 340 Sponsor: Relmada Therapeutic (RLMD)	Commercial: FAILURE (commercially insufficient additive clinical benefit)		Classification: True Negative (TN)
1739	Anitocabtagene-autoleucl NCTID: NCT05396885 Phase: Phase 2 Class: First-In-Class Modality: CAR-T therapy MoA: anti-BCMA D-Domain CAR-T cell therapy Area: Neoplasms Indication: Relapsed or Refractory Multiple Myeloma Human Patients: 110 Sponsor: Arcellx (ACLX)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS non-superior to Carvykti) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in CR/OS non-superior to Carvykti)	Readout: 9 Dec 2024 Lead Time: 121 days in advance Interpretation: anito-cell achieved 97% ORR and 62% CR/sCR; non-superior to Carvykti that achieved 98% ORR and 67% sCR	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (non-superior to Carvykti) Classification: True Negative (TN)
1685	tirzepatide NCTID: NCT05822830 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R/GIPR-biased dual agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 700 Sponsor: Eli Lilly and Company (LLY)	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: SUCCESS (statistically significant clinical benefit in overall weight reduction superior to semaglutide) Commercial: SUCCESS (commercially sufficient clinical benefit in stratified weight reduction superior to semaglutide)	Readout: 4 Dec 2024 Lead Time: 140 days in advance Interpretation: tirzepatide achieved 20.2% weight loss at week 72; which is superior to semaglutide that achieved 13.7% weight loss at week 72 as the active control arm; tirzepatide achieved superiority over semaglutide in all the five key secondary endpoints (e.g. 31.6% of people taking tirzepatide achieved at least 25% body weight loss compared to 16.1% of those taking semaglutide)	Correct Prediction Conclusion: statistically significant (weight loss) and commercially sufficient (superior to semaglutide's efficacy) Classification: True Positive (TP)
383	REL-1017 NCTID: NCT04855747 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: GLUN1-GLUN2D antagonist Area: Mental Disorders Indication: Major Depressive Disorder Depression (MDD) Human Patients: 340 Sponsor: Relmada Therapeutics (RLMD)	Date: 14 Jul 2024 Quarter: Q3'24 Batch 17 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 4 Dec 2024 Lead Time: 143 days in advance Interpretation: REL-1017 is found unlikely to meet the primary efficacy endpoint of adding significant clinical benefit in MADRS10 score	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1763	Namilumab NCTID: NCT05314517 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-GM-CSF mAb inhibitor Area: Respiratory Tract Diseases Indication: Chronic Pulmonary Sarcoidosis Human Patients: 107 Sponsor: Roivant Sciences (ROIV)	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in sarcoidosis worsening against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in sarcoidosis worsening inferior to oral corticosteroid)	Readout: 3 Dec 2024 Lead Time: 104 days in advance Interpretation: namilumab failed to achieve the primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1175	RMC-6236 NCTID: NCT05379985 Phase: Phase 1 Class: First-In-Class	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: -	Readout: 2 Dec 2024 Lead Time: 505 days in advance Interpretation: RMC6236 achieved 9% ORR (9% ORR is low and	Correct Prediction Conclusion: statistically maybe significant and commercially probably insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule MoA: tri-complex RAS(ON) multi-selective inhibitor Area: Neoplasms Indication: RAS Mutant Advanced Solid Tumors Human Patients: 614 Sponsor: Revolution Medicines (RVMD)	Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	probably non-superior to KRAS(OFF) G12C inhibitors)	Classification: True Negative (TN)
1176	RMC-6291 NCTID: NCT05462717 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: tri-complex RAS(ON) multi-selective inhibitor Area: Neoplasms Indication: Colorectal Cancer (CRC) patients previously treated with KRAS(OFF) G12C inhibitors Human Patients: 222 Sponsor: Revolution Medicines (RVMD)	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: - Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 2 Dec 2024 Lead Time: 505 days in advance Interpretation: RMC6291 achieved 0% ORR (0% ORR means non-superior to KRAS(OFF) G12C inhibitors)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
985	NovoTTF-200T NCTID: NCT03377491 Phase: Phase 3 Class: First-In-Class Modality: medical device MoA: a device delivering low-intensity; wave-like; alternating electric fields to tumor sites Area: Neoplasms Indication: Pancreatic Cancer Human Patients: 571 Sponsor: Novocure (NVCR)	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 2 Dec 2024 Lead Time: 103 days in advance Interpretation: TTFields + SoC achieved 16.20 months mOS compared with 14.16 months in patients who received SoC alone (p=0.039); no PFS data announced in topline readout (usually indicating unremarkable PFS data)	Correct Prediction Conclusion: statistically significant (PFS data pending) and commercially sufficient (weakly superior OS) Classification: True Positive (TP)
1669	JANX007 NCTID: NCT05519449 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-PSMA/CD3 protease-activated albumin-binding TCE Area: Neoplasms Indication: Metastatic Castration-Resistant Prostate Cancer (mCRPC) Human Patients: 105 Sponsor: Janux Therapeutics (JANX)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant yet weak clinical benefit in ORR/PFS/rPFS against placebo) Commercial: partial FAILURE (commercially insufficient clinical benefit in ORR/PFS/rPFS inferior to Pluvicto) partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in OS maybe superior to Pluvicto)	Readout: 2 Dec 2024 Lead Time: 146 days in advance Interpretation: JANX007 achieved 7.4 months PFS (median 5L); which is inferior to 8.5months PFS achieved by Lu-117-PSMA-617 + SoC (median 3L); JANX007 probably achieved 25% confirmed ORR (2/8; inferred from the reported 50% ORR that glossed over the number of confirmed and unconfirmed responses); which is inferior to 30% ORR achieved by Lu-117-PSMA-617 + SoC (median 3L)	Correct Prediction Conclusion: statistically significant yet weak and commercially TBD (wait for OS data) Classification: True Negative (TN)
1442	MariTide (AMG133) NCTID: NCT05669599 Phase: Phase 2 Class: First-In-Class Modality: antibody fragment biologic MoA: antibody-peptide conjugate that activates GLP1R via peptide and inhibits GIPR via antibody Area: Nutritional and Metabolic Diseases Indication: Obesity Overweight Type 2 Diabetes Mellitus Human Patients: 592	Date: 3 Feb 2024 Quarter: Q3'24 Batch 11 Technical: partial SUCCESS (statistically significant clinical benefit in weight loss) partial FAILURE (statistically insignificant clinical benefit in HbA1c reduction) Commercial: FAILURE (commercially insufficient clinical benefit due to inferior-to-tirzepatide/semaglutide long-term detrimental toxicity for both nondiabetic and diabetic patients; despite superior-to-tirzepatide/semaglutide	Readout: 26 Nov 2024 Lead Time: 297 days in advance Interpretation: MariTide achieved 20% weight loss with 11% TEAE-related discontinuation for obese nondiabetic patients; numerically superior to the tirzepatide's 19.5% weight loss yet inferior to tirzepatide 6.2% TEAE-related discontinuation for obese nondiabetic patients at week 52 (10.1056/NEJMoa2206038); superior to the semaglutide's 13.4% weight loss yet inferior to semaglutide's 5-8% TEAE-related	Correct Prediction Conclusion: statistically significant(weight loss) and commercially insufficient (inferior to tirzepatide/semaglutide tolerability) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Amgen (AMGN)	efficacy in morbid weight loss)	discontinuation for obese nondiabetic patients at week 52 (see add link for semaglutide's data on Lancet)	
1761	Capivasertib NCTID: NCT04493853 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: pan-ATK small molecule inhibitor Area: Neoplasms Indication: Hormone-Sensitive Prostate Cancer Human Patients: 1012 Sponsor: AstraZeneca (AZN)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in rPFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 26 Nov 2024 Lead Time: 99 days in advance Interpretation: capivasertib + SoC achieved superior rPFS compared with SoC alone; OS data not mature	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1429	Tiragolumab NCTID: NCT04294810 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-TIGIT mAb inhibitor Area: Neoplasms Indication: Non-Small Cell Lung Cancer Human Patients: 620 Sponsor: Roche Group (RHHBY)	Date: 18 Jan 2024 Quarter: Q1'24 Batch 16 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 26 Nov 2024 Lead Time: 313 days in advance Interpretation: tiragolumab failed to achieve additive clinical benefit in OS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
568	PTC857 NCTID: NCT05349721 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: ALOX15 inhibitor Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis (ALS) Human Patients: 307 Sponsor: PTC Therapeutics (PTCT)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 1 Technical: FAILURE (statistically insignificant additive clinical benefit in ALSFRS-R) Commercial: FAILURE (commercially insufficient additive clinical benefit in ALSFRS-R)	Readout: 26 Nov 2024 Lead Time: 112 days in advance Interpretation: PTC857 failed to achieve any primary or secondary efficacy endpoints	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1621	Taldefgrobep alfa NCTID: NCT05337553 Phase: Phase 3 Class: First-In-Class Modality: recombinant protein biologic MoA: selective ACVR2B antagonist Area: Nervous System Diseases Indication: Spinal Muscular Atrophy (SMA) Human Patients: 269 Sponsor: Biohaven (BHAVN)	Date: 15 May 2024 Quarter: Q3'24 Batch 11 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit in MFM32)	Readout: 25 Nov 2024 Lead Time: 194 days in advance Interpretation: taldefgrobep alfa + SoC failed to achieved the MFM32 primary efficacy endpoint at week 48 compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
580	AL002 NCTID: NCT04592874 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-TREM2 mAb activator Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 381 Sponsor: Alector / AbbVie (ALEC/ABBV)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to lecanemab)	Readout: 25 Nov 2024 Lead Time: 111 days in advance Interpretation: AL002 failed to meet primary efficacy endpoints CDR-SB	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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#	Clinical Trial	Certified Prediction	Validation	Result
1724	Simufilam NCTID: NCT04994483 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: misfolded FLNA inhibitor Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 804 Sponsor: Cassava Sciences (SAVA)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ADAS-COG12/ADCS-ADL23 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in ADAS-COG12/ADCS-ADL23 inferior to lecanemab)	Readout: 25 Nov 2024 Lead Time: 111 days in advance Interpretation: simufilam failed to meet primary efficacy endpoints ADAS-COG12 and ADCS-ADL at week 52	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1383	SAGE-718 (dalzanemdor) NCTID: NCT05107128 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: NMDAR PAM Area: Nervous System Diseases Indication: Huntington's Disease Human Patients: 189 Sponsor: Sage Therapeutics (SAGE)	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Nov 2024 Lead Time: 214 days in advance Interpretation: dalzanemdor failed to meet the primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1596	obicetrapib NCTID: NCT06005597 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective CETP inhibitor Area: Nutritional and Metabolic Diseases Indication: familial hypercholesterolemia (HeFH) and/or atherosclerotic cardiovascular disease (ASCVD) Human Patients: 407 Sponsor: NewAmsterdam Pharma (NAMS)	Date: 12 May 2024 Quarter: Q1'25 Batch 4 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit of obicetrapib in LDL-C reduction) Commercial: FAILURE (commercially insufficient additive clinical benefit of obicetrapib in MACE with significantly increased toxicity-driven mortality; The MACE-based clinical benefit of obicetrapib + ezetimibe + SoC is inferior to that of SoC + ezetimibe or SoC alone)	Readout: 20 Nov 2024 Lead Time: 192 days in advance Interpretation: obicetrapib + ezetimibe + SoC achieved 48.6% LDL-C reduction at day 84; which is superior to ezetimibe + SoC or SoC alone (yet weaker than 54-59% reduction as the market consensus for strong efficacy); obicetrapib achieved 7% TEAE; which is inferior to ezetimibe + SoC (3%) or SoC alone (4%)	Correct Prediction Conclusion: statistically significant yet weak and commercially TBD (no MACE data available) Classification: True Positive (TP)
1484	PYX-201 NCTID: NCT05720117 Phase: Phase 1 Class: First-In-Class Modality: ADC MoA: anti-fibronectin-EDB ADC with cathepsin B-cleavage mediated release of auristatin payload Area: Neoplasms Indication: advanced solid tumor Human Patients: 80 Sponsor: Pyxis Oncology (PYXS)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: FAILURE (statistically insignificant clinical benefit in PFS/OS/ORR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Nov 2024 Lead Time: 225 days in advance Interpretation: PYX201 achieved 26% ORR for advanced solid tumors; which is inferior to other targeted therapies for advanced solid tumors; e.g. 56% ORR of Enhertu for HER2+ advanced solid tumors (refer to additional press link for AstraZeneca's data)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient (weak efficacy) Classification: True Negative (TN)
1752	linerixibat NCTID: NCT04950127 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: ASBT/IBAT inhibitor Area: Immune System Diseases Indication: Cholestatic Pruritus (CP) Human Patients: 238 Sponsor: GSK (GSK)	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in cholestatic pruritus against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in cholestatic pruritus non-superior non-inferior to odevixibat/volixibat)	Readout: 19 Nov 2024 Lead Time: 98 days in advance Interpretation: linerixibat achieved the primary endpoint of itch score reduction at week 24 (no specific data or p-value disclosed)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: True Positive (TP)
1562	Dapirolizumab Pegol	Date: 26 Apr 2024 Quarter: Q3'24 Batch 3	Readout: 19 Nov 2024 Lead Time: 207 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT04294667 Phase: Phase 3 Class: First-In-Class Modality: fab biologic MoA: anti-CD40L PEGylated fab Area: Immune System Diseases Indication: Systemic Lupus Erythematosus (SLE) Human Patients: 321 Sponsor: UCB SA (UCB)	Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Interpretation: dapirolizumab achieved 14.9% placebo-adjusted BICLA at week 48 as an add-on the SoC (p=0.011) yet the key secondary endpoint BICLA at week 24 not met (usually BICLA at week 24 is the primary efficacy endpoint).	Conclusion: statistically insignificant (in BICLA at week 24) and commercially insufficient Classification: True Negative (TN)
1709	NGN101 NCTID: NCT05228145 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV9-delivered CLN5 trans gene Area: Nervous System Diseases Indication: CLN5 Batten Disease Human Patients: 6 Sponsor: Neurogene (NGNE)	Date: 31 Jul 2024 Quarter: Q4'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in UBDRS or visual acuity) Commercial: FAILURE (commercially insufficient clinical benefit in UBDRS or visual acuity)	Readout: 18 Nov 2024 Lead Time: 110 days in advance Interpretation: NGN101's further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1584	INCB000262 (EP262) NCTID: NCT06077773 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MRGPRX2 antagonist Area: Immune System Diseases Indication: chronic spontaneous urticaria (CSU) Human Patients: 154 Sponsor: Incyte Corporation (INCY)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 16 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-barzolvolimab efficacy)	Readout: 18 Nov 2024 Lead Time: 204 days in advance Interpretation: enrolment paused due to preclinical toxicity findings of INCB000262	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1575	INCB000547 (EP547) NCTID: NCT05525520 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MRGPRX4 antagonist Area: Immune System Diseases Indication: Cholestatic Pruritus (CP) Human Patients: 62 Sponsor: Incyte Corporation (INCY)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in cholestatic pruritus reduction with a negative dose-response relationship) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-SoC efficacy in cholestatic pruritus reduction)	Readout: 18 Nov 2024 Lead Time: 204 days in advance Interpretation: INCB000547's further development will be discontinued due to weak clinical benefit (no detailed data disclosure)	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1684	Tirzepatide (LY3298176) NCTID: NCT04847557 Phase: Phase 3 Class: First-In-Class Modality: synthetic peptide MoA: GLP1R/GIPR-biased dual agonist Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Heart Failure With Preserved Ejection Fraction (HFpEF) and Obesity Human Patients: 731 Sponsor: Eli Lilly and Company (LLY)	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: SUCCESS (statistically significant additive clinical benefit in KCCQ/mortality/heart failure as an adjunctive therapy) Commercial: SUCCESS (commercially sufficient additive clinical benefit in 6MWD superior to semaglutide as an adjunctive therapy)	Readout: 16 Nov 2024 Lead Time: 122 days in advance Interpretation: -38% risk reduction in composite endpoint (DOI-10.1056/NEJMoa2410027) and 6.8-9.8 point improvement in KCCQ-CSS by week 52 (vs 7.5 by week 52 for semaglutide in Butler et Al. 2024 LANCET); 30.3m and 15.9m placebo-adjusted efficacy/regimen 6WMD (vs 18.2m and 14.3m achieved by semaglutide by week 52 Butler et Al. 2024 LANCET)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1103	OTX-2002 NCTID: NCT05497453	Date: 27 Feb 2024 Quarter: Q2'24 Batch 9	Readout: 14 Nov 2024 Lead Time: 261 days in advance	Correct Prediction Conclusion: statistically probably

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 1 Phase 2 Class: First-In-Class Modality: mRNA medicine MoA: LNP-encapsulated mRNAs of ZF-DNMT and ZF-KRAB proteins Area: Neoplasms Indication: advanced solid tumor Human Patients: 190 Sponsor: Omega Therapeutics (OMGA)	Technical: partial SUCCESS (statistically significant yet weak clinical benefit for OTX2002 monotherapy and OTX2002 combotherapies) Commercial: FAILURE (commercially insufficient additive clinical benefit due to the inferior-to-atezolizumab+b evacizumab efficacy of OTX2002 combotherapies)	Interpretation: OTX2002 achieved 50% DCR for HCC in line with historical benchmark range for approved TKIs and PD1 monotherapies (29-65%) and its further development is discontinued	significant and commercially insufficient (weak efficacy) Classification: True Negative (TN)
1371	NXP800 NCTID: NCT05226507 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: anti-HSF1 inhibitor Area: Neoplasms Indication: ADRI1a-mutated ovarian cancer Human Patients: 61 Sponsor: Nuvectis Pharma (NVCT)	Date: 8 Dec 2023 Quarter: Q1'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Nov 2024 Lead Time: 342 days in advance Interpretation: NXP800 achieved at most 9% ORR (1/11 unconfirmed); which is non-superior to the 8-13% ORR by nivolumab or PLD/GEM (Journal of Clinical Oncology DOI-10.1200/JCO.21.00334)	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)
1604	LTI-03 NCTID: NCT05954988 Phase: Phase 1 Class: First-In-Class Modality: peptide MoA: CAV1-like peptide Area: Respiratory Tract Diseases Indication: Idiopathic Pulmonary Fibrosis (IPF) Human Patients: 24 Sponsor: Aileron Therapeutics (ALRN)	Date: 12 May 2024 Quarter: Q3'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-bexotegrest efficacy in FVC)	Readout: 13 Nov 2024 Lead Time: 185 days in advance Interpretation: LTI03 is safe and achieved statistical significant in four of eight IPF biomarkers for cohort 1 and cohort 2	Correct Prediction Conclusion: statistically significant (safety) and commercially TBD Classification: True Positive (TP)
1779	Letetresgene autoleucel (lete-cel; GSK3377794) NCTID: NCT03967223 Phase: Phase 2 Class: First-In-Class Modality: cell therapy MoA: anti-NY-ESO-1 TCR T-cell therapy Area: Neoplasms Indication: advanced synovial sarcoma (SS) or myxoid/round cell liposarcoma (MRCLS) Human Patients: 103 Sponsor: Adaptimmune Therapeutics (ADAP)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet moderate additive clinical benefit in ORR/PFS as 1L treatment with moderate toxicity) SUCCESS (statistically significant additive clinical benefit in ORR/PFS as 2L treatment with moderate toxicity) Commercial: partial FAILURE (commercially insufficient additive clinical benefit in OS as 1L treatment) partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS as 2L treatment)	Readout: 13 Nov 2024 Lead Time: 65 days in advance Interpretation: lete-cel + SoC as 2L treatment achieved 42% ORR and 5.3 months PFS which is superior to the SoC alone (1L data not reported)	Correct Prediction Conclusion: statistically significant (2L) and commercially TBD (2L OS not mature) Classification: True Positive (TP)
1616	Pimicotinib(ABSK021) NCTID: NCT05804045 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: anti-CSF1R inhibitor Area: Neoplasms Indication: tenosynovial giant cell tumor (TGCT) Human Patients: 90 Sponsor: Merck KGaA (MKKGY)	Date: 14 May 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to pexidartinib)	Readout: 12 Nov 2024 Lead Time: 182 days in advance Interpretation: pimicotinib achieved 50.8% placebo-adjusted ORR at week 25 (p<0.0001); which is superior to pexidartinib's 39% placebo-adjusted ORR at week 25 (P<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient; correct prediction Classification: True Positive (TP)
1624	Tamibarotene	Date: 15 May 2024 Quarter: Q3'24 Batch 10	Readout: 12 Nov 2024 Lead Time: 181 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT04797780 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: RARalpha agonist Area: Neoplasms Indication: Myelodysplastic Syndrome with RARA gene overexpression Human Patients: 550 Sponsor: Syros Pharmaceuticals (SYRS)	Technical: FAILURE (statistically insignificant additive clinical benefit in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	Interpretation: Tamibarotene failed to achieve additional benefit in CR as the primary efficacy endpoint	Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
943	Revumenib (SNDX-5613) NCTID: NCT04065399 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MENIN-MLL1 inhibitor Area: Neoplasms Indication: mNPM1-mutant relapsed/refractory Leukemias Human Patients: 413 Sponsor: Syndax Pharmaceuticals (SNDX)	Date: 18 Jun 2023 Quarter: 2H'23 Batch 6 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Nov 2024 Lead Time: 513 days in advance Interpretation: Revumenib achieved 23% CR/CRh; which is inferior to CLT019's 81% CR	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior efficacy compared with SoC) Classification: True Negative (TN)
1710	NGN-401 NCTID: NCT05898620 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV9-delivered miRNA-regulated MECP2 gene therapy Area: Nervous System Diseases Indication: Rett Syndrome Human Patients: 16 Sponsor: Neurogene (NGNE)	Date: 31 Jul 2024 Quarter: Q4'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Nov 2024 Lead Time: 103 days in advance Interpretation: low-dose NGN401 achieved 2-score CGI-I from baseline; high-dose NGN401 achieved 33.3% SAE (1/3)	Correct Prediction Conclusion: statistically probably significant (yet weak overall clinical benefit considering both efficacy and toxicity) and commercially probably insufficient Classification: True Negative (TN)
1457	Emraclidine (CVL-231) NCTID: NCT05227703 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: a selective CNS-penetrant CHRM4 PAM Area: Nervous System Diseases Indication: schizophrenia Human Patients: 372 Sponsor: AbbVie (ABBV)	Date: 14 Feb 2024 Quarter: Q3'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Nov 2024 Lead Time: 271 days in advance Interpretation: emraclidine failed to achieved the primary efficacy endpoint PANSS at week 6	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1458	Emraclidine (CVL-231) NCTID: NCT05227690 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: a selective CNS-penetrant CHRM4 PAM Area: Nervous System Diseases Indication: schizophrenia Human Patients: 372 Sponsor: AbbVie (ABBV)	Date: 14 Feb 2024 Quarter: Q3'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Nov 2024 Lead Time: 271 days in advance Interpretation: emraclidine failed to achieved the primary efficacy endpoint PANSS at week 6	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1444	tezepelumab NCTID: NCT04851964 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody	Date: 5 Feb 2024 Quarter: Q3'24 Batch 11 Technical: SUCCESS (statistically significant yet moderate additive clinical benefit)	Readout: 8 Nov 2024 Lead Time: 277 days in advance Interpretation: tezepelumab achieved the efficacy primary endpoint of total endoscopic nasal polyp score at	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: anti-TSLP inhibitor Area: Respiratory Tract Diseases Indication: pancreas Neoplasm Stomach Neoplasm Gastrointestinal Neoplasms Digestive System Neoplasm Neoplasms by Site Neoplasms Human Patients: 416 Sponsor: Amgen / AstraZeneca (AMGN/AZN)	Commercial: SUCCESS (commercially sufficient yet moderate additive clinical benefit)	week 52 and mean nasal obstruction score by week 52	
1780	Mipasetamab Uzoptirine (ADCT-601) NCTID: NCT05389462 Phase: Phase 1 Class: First-In-Class Modality: ADC MoA: anti-AXL ADC conjugated with a PBD-dimer cytotoxin SG3199 Area: Neoplasms Indication: advanced solid tumours Human Patients: 128 Sponsor: ADC Therapeutics (ADCT)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS for advanced solid tumors regardless of AXL amplification status in 2L/3L clinical settings) SUCCESS (statistically significant clinical benefit in ORR/PFS superior to chemotherapy for advanced solid tumors with AXL amplification in 2L/3L clinical settings) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS for advanced solid tumors regardless of AXL amplification status in 2L/3L clinical settings) partial FAILURE (commercially maybe sufficient yet very weak clinical benefit in OS at most numerically superior to chemotherapy for advanced solid tumors with AXL amplification in 2L/3L clinical settings)	Readout: 7 Nov 2024 Lead Time: 59 days in advance Interpretation: ADCT601's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1471	NKX019 NCTID: NCT05020678 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: allogeneic anti-CD19 CAR-NK cell therapy Area: Neoplasms Indication: relapsed/refractory B cell malignancies Human Patients: 150 Sponsor: Nkarta (NKTX)	Date: 15 Feb 2024 Quarter: Q2'24 Batch 6 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to anti-CD19 CAR-T cell therapies)	Readout: 7 Nov 2024 Lead Time: 266 days in advance Interpretation: NKX019's further development has been forgone based on data review	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1217	SRP-5051 NCTID: NCT04004065 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Menin-MLL1 inhibitor Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 62 Sponsor: Sarepta Therapeutics (SRPT)	Date: 11 Aug 2023 Quarter: 2H'23 Batch 12 Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin level) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD)	Readout: 6 Nov 2024 Lead Time: 453 days in advance Interpretation: SRP5051 resulted in a mean absolute dystrophin expression of 5.17% at week 28; yet its further development has been discontinued due to unremarkable benefit-risk data	Correct Prediction Conclusion: statistically partially significant (dystrophin expression) and commercially insufficient (weak efficacy) Classification: True Negative (TN)
1018	TNG462 NCTID: NCT05732831 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor Area: Neoplasms	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: SUCCESS (commercially sufficient clinical benefit in OS)	Readout: 6 Nov 2024 Lead Time: 101 days in advance Interpretation: TNG462 achieved 43% ORR for relapsed/refractory cholangiocarcinoma; superior to 5% ORR achieved by second-line chemotherapy for advanced biliary tract cancer; including cholangiocarcinoma (Lancet DOI-	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: MTAP-deleted Solid Tumors Human Patients: 159 Sponsor: Tango Therapeutics (TNGX)		10.1016/S1470-2045(21)00027-9	
1019	TNG908 NCTID: NCT05275478 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor Area: Neoplasms Indication: MTAP-deleted Solid Tumors Human Patients: 192 Sponsor: Tango Therapeutics (TNGX)	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in OS)	Readout: 6 Nov 2024 Lead Time: 101 days in advance Interpretation: TNG908 exhibited overall weak efficacy (active for non-CNS solid tumors yet inactive for GBM)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: True Negative (TN)
357	Lumateperone NCTID: NCT04959032 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: 5HT2AR antagonist Area: Nervous System Diseases Indication: Schizophrenia relapse prevention Human Patients: 228 Sponsor: Intra-Cellular Therapies (ITCI)	Date: 23 Sep 2022 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 5 Nov 2024 Lead Time: 774 days in advance Interpretation: Lumateperone achieved a 22.2% placebo-adjusted lower relapse of schizophrenia (16.4% vs 38.6%; p=0.0002)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1759	AZD5004 NCTID: NCT06555822 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 15 Sponsor: AstraZeneca (AZN)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: partial FAILURE (statistically significant clinical benefit in weight reduction for healthy obese patients against placebo despite being at least numerically inferior to orforglipron/GSBR1290) Commercial: partial SUCCESS (commercially sufficient clinical benefit in muscle retention and cardio protection for healthy obese patients at least numerically superior to orforglipron/GSBR1290)	Readout: 5 Nov 2024 Lead Time: 78 days in advance Interpretation: AZD5004 achieved 5.8% weight reduction in more than four weeks (no placebo arm data); thus inferior to VK2735's 6.8% weight reduction at day 28 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient Classification: True Negative (TN)
1497	AZD6234 NCTID: NCT06132841 Phase: Phase 1 Class: First-In-Class Modality: peptide MoA: long-lasting amylin analog Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 76 Sponsor: AstraZeneca (AZN)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in weight loss) Commercial: FAILURE (commercially insufficient clinical benefit for repeated-dose AZD6234; which is inferior to semaglutide with increasing toxicity for elderly obese population with comorbidities)	Readout: 5 Nov 2024 Lead Time: 244 days in advance Interpretation: AZD6234 achieved statistically significant reduction in weight compared to placebo (no specific number or p-value)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (no disclosure of data usually indicates weak efficacy) Classification: True Negative (TN)
1496	AZD6234 NCTID: NCT05511025 Phase: Phase 1 Class: First-In-Class Modality: peptide MoA: long-lasting amylin analog Area: Nutritional and Metabolic	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in weight loss) Commercial: FAILURE (commercially	Readout: 5 Nov 2024 Lead Time: 244 days in advance Interpretation: AZD6234 achieved statistically significant reduction in weight compared to placebo (no specific number or p-value)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (no disclosure of data usually indicates weak efficacy) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Diseases Indication: Obesity Human Patients: 54 Sponsor: AstraZeneca (AZN)	insufficient clinical benefit for single-dose AZD6234+acetaminophen; which is non-inferior to semaglutide for nondiabetic obese population and inferior to semaglutide for diabetic obese population)		
1298	SC291 NCTID: NCT05878184 Phase: Phase 1 Class: Best-In-Class Modality: CAR-T therapy MoA: anti-CD19 CAR T cell therapy Area: Neoplasms Indication: r/r B-cell malignancies Human Patients: 16 Sponsor: Sana Biotechnology (SANA)	Date: 21 Oct 2024 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit due to inferior efficacy for NHL and non-superior efficacy for CLL compared with other anti-CD19 CAR T cell therapies)	Readout: 4 Nov 2024 Lead Time: 14 days in advance Interpretation: SC291 development discontinued without further disclosure of data	Correct Prediction Conclusion: statistically probably significant and commercially insufficient Classification: True Negative (TN)
1330	Setmelanotide NCTID: NCT04963231 Phase: Phase 2 Class: First-In-Class Modality: peptide MoA: MC4R agonist Area: Nutritional and Metabolic Diseases Indication: Hypothalamic Obesity Human Patients: 164 Sponsor: Rhythm Pharmaceuticals (RYTM)	Date: 20 Nov 2023 Quarter: 2H'23 Batch 29 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 4 Nov 2024 Lead Time: 350 days in advance Interpretation: setmelanotide achieved 55% placebo-adjusted higher proportion of patients who achieved 5% BMI reduction	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1523	Semaglutide NCTID: NCT04822181 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Non-alcoholic Steatohepatitis Human Patients: 1200 Sponsor: Novo Nordisk (NVO)	Date: 24 Mar 2024 Quarter: Q3'24 Batch 18 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient yet modest clinical benefit of semaglutide inferior-to-tirzepatide/efruxifermin for non-cirrhotic NASH)	Readout: 1 Nov 2024 Lead Time: 222 days in advance Interpretation: Semaglutide achieved 14.5% placebo-adjusted fibrosis improvement with no worsening of steatohepatitis and 28.8% placebo-adjusted steatohepatitis resolution with no worsening of fibrosis at week 72; inferior to tirzepatide's 21% and 52% delta at week 52 (DOI-10.1056/NEJMoa2401943) ; and inferior to efruxifermin's 21% and 61% delta at week 24 (see 10.1001/jamanetworkopen.2022.31982)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to tirzepatide/efruxifermin) Classification: True Negative (TN)
1353	Efgartigimod NCTID: NCT05810961 Phase: Phase 2 Class: First-In-Class Modality: antibody fragment biologic MoA: FcRn receptor inhibitor Area: Immune System Diseases Indication: Membranous Nephropathy Human Patients: 8 Sponsor: argenx (ARGX)	Date: 30 Nov 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant yet moderate clinical benefit in UPCR) partial FAILURE (statistically insignificant clinical benefit in eGFR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 31 Oct 2024 Lead Time: 336 days in advance Interpretation: efgartigimod failed to achieve sufficient clinical benefit and further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1569	Bepranemab NCTID: NCT04867616 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody	Date: 26 Apr 2024 Quarter: Q3'24 Batch 3 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in CDR-SB)	Readout: 31 Oct 2024 Lead Time: 188 days in advance Interpretation: Bepranemab did not meet the primary efficacy endpoint CDR-SB.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view: **Oncology** Immunology Metabolic Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: anti-tau mAb inhibitor Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 466 Sponsor: UCB Biopharma (UCB)	for early AD patients) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-donanemab/lecanemab in CDR-SB for early AD patients)		Classification: True Negative (TN)
1788	Trontinemab (RO7126209) NCTID: NCT04639050 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: bispecific antibody MoA: bispecific anti-abeta and anti-TfR1 antibody Area: Nervous System Diseases Indication: Mild to Moderate Alzheimer's Disease Human Patients: 285 Sponsor: Roche Group (RHHBY)	Date: 15 Sep 2024 Quarter: Q4'24 Batch 17b Technical: SUCCESS (statistically significant clinical benefit in brain amyloid load reduction) Commercial: FAILURE (commercially insufficient clinical benefit in CDR-SB/ADAS-Cog13 inferior to lecanemab)	Readout: 30 Oct 2024 Lead Time: 45 days in advance Interpretation: trontinemab achieved strong effect in amyloid load reduction at week 28 (-107 CL at 36 mg/kg vs -3 CL in placebo); no data available for CDR-SB/ADAS-Cog13	Correct Prediction Conclusion: statistically significant (in amyloid beta reduction) and commercially TBD (wait for CDR-SB/ADAS-Cog13 data) Classification: True Positive (TP)
1448	Fipaxalparant (HZN825) NCTID: NCT05032066 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: LPAR1 antagonist Area: Respiratory Tract Diseases Indication: Idiopathic Pulmonary Fibrosis (IPF) Human Patients: 153 Sponsor: Amgen (AMGN)	Date: 5 Feb 2024 Quarter: Q3'24 Batch 11 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to bexotegast)	Readout: 30 Oct 2024 Lead Time: 268 days in advance Interpretation: fipaxalparant failed to achieve any primary/secondary endpoints and further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
546	Relacorilant NCTID: NCT04308590 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral non-steroidal glucocorticoid receptor antagonist Area: Endocrine System Diseases Indication: Hypercortisolism Human Patients: 137 Sponsor: Concept Therapeutics (CORT)	Date: 16 Jul 2023 Quarter: 2H'23 Batch 10 Technical: FAILURE (statistical insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 30 Oct 2024 Lead Time: 472 days in advance Interpretation: relacorilant failed to achieve the mean SBP primary efficacy endpoint against placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
711	Peresolimab NCTID: NCT05516758 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: PD1 agonist Area: Immune System Diseases Indication: Rheumatoid Arthritis Human Patients: 491 Sponsor: Eli Lilly and Company (LLY)	Date: 26 Nov 2022 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 30 Oct 2024 Lead Time: 704 days in advance Interpretation: peresolimab terminated without data disclosure despite positive phase2a data in 2023 (DOI- 10.1056/NEJMoa2209856)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1696	aldesleukin NCTID: NCT06096090 Phase: Phase 2 Class: First-In-Class Modality: peptide MoA: low-dose recombinant IL2 Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 40	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: FAILURE (statistically insignificant clinical benefit in ADAS-Cog13 or CDR-SB) Commercial: FAILURE (commercially insufficient clinical benefit in ADAS-Cog13 or CDR-SB)	Readout: 29 Oct 2024 Lead Time: 97 days in advance Interpretation: aldesleukin failed to meet the exploratory efficacy endpoints ADAS-Cog14 or CDR-SOB	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Coya Therapeutics (COYA)			
1441	Uproleselan (GMI-1271) NCTID: NCT03616470 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective E-selectin antagonist Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 388 Sponsor: GlycoMimetics (GLYC)	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 29 Oct 2024 Lead Time: 256 days in advance Interpretation: uproleselan failed to achieve the EFS primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1765	RMC-9805 NCTID: NCT06040541 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: KRAS-G12D-ON inhibitor Area: Neoplasms Indication: KRAS G12D-Mutant Solid Tumors Human Patients: 444 Sponsor: Revolution Medicines Inc. (RVMD)	Date: 27 Aug 2024 Quarter: Q4'24 Batch 14 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS superior to tumor-specific SoC) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS non-superior to tumor-specific SoC)	Readout: 25 Oct 2024 Lead Time: 59 days in advance Interpretation: RMC9805 achieved 30% ORR; where is superior to the SoC chemotherapy's 9%-16% ORR (see add'l link below)	Correct Prediction Conclusion: statistically significant (superior in ORR) and commercially TBD (OS data not mature) Classification: True Positive (TP)
1700	TYRA-300 NCTID: NCT05544552 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: N540K-mutation-specific FGFR3 antagonist Area: Neoplasms Indication: Advanced Urothelial Carcinoma and Other Solid Tumors With FGFR3 Gene Alterations Human Patients: 310 Sponsor: Tyra Biosciences (TYRA)	Date: 27 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS with superior-to-erdafitinib safety) Commercial: SUCCESS (commercially sufficient clinical benefit in OS/CR superior to erdafitinib)	Readout: 25 Oct 2024 Lead Time: 90 days in advance Interpretation: TYRA300 achieved 54.5% ORR and 10% SAE (Gr3 only no Gr4); superior to erdafitinib's 71% SAE (both Gr3 and Gr4) (Lancet DOI- 10.1016/S1470-2045(21)00660-4)	Correct Prediction Conclusion: statistically significant (superior in safety) and commercially TBD (OS data not mature) Classification: True Positive (TP)
1202	Ganaxalone NCTID: NCT05323734 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: 3beta-methylated synthetic analog of allopregnanolone Area: Nervous System Diseases Indication: Tuberous Sclerosis Complex related Epilepsy Human Patients: 128 Sponsor: Marinus Pharmaceuticals (MRNS)	Date: 14 Jul 2024 Quarter: Q3'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in seizure frequency) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 24 Oct 2024 Lead Time: 102 days in advance Interpretation: ganaxalone did not meet the primary efficacy endpoint of seizure frequency despite numerical improvement (p=0.09)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1130	naporafenib (ERAS254) NCTID: NCT05907304 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: RAF inhibitor Area: Neoplasms Indication: RAS-mutant advanced solid tumors Human Patients: 115	Date: 25 Jun 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 24 Oct 2024 Lead Time: 487 days in advance Interpretation: naporafenib + trametinib achieved only 30% ORR; non-superior to trametinib monotherapy that achieved 33% ORR for advanced melanoma (10.1002/onco.13795)	Correct Prediction Conclusion: statistically insignificant (in ORR) and commercially TBD (OS data not mature) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Erasca (ERAS)			
1718	ALTO-100 NCTID: NCT05712187 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: BDNF activator Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 301 Sponsor: Alto Neuroscience (ANRO)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak (additive) clinical benefit in MADRS) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in MADRS inferior to lumateperone)	Readout: 22 Oct 2024 Lead Time: 77 days in advance Interpretation: ALTO100 did not meet the primary efficacy endpoint MADRS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1532	Semaglutide NCTID: NCT03914326 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Cardiovascular Outcomes with Type 2 Diabetes Human Patients: 9651 Sponsor: Novo Nordisk (NVO)	Date: 24 Mar 2024 Quarter: Q3'24 Batch 18 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 21 Oct 2024 Lead Time: 211 days in advance Interpretation: Semaglutide achieved 14% placebo-adjusted reduction in MACE (no FDA-approved SoC)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1329	NX-5948 NCTID: NCT05131022 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: BTK degrader Area: Neoplasms Indication: Relapsed/Refractory B-cell Malignancies Human Patients: 292 Sponsor: Nurix Therapeutics (NRIX)	Date: 20 Nov 2023 Quarter: 2H'23 Batch 28 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to SoC BTK inhibitors)	Readout: 19 Oct 2024 Lead Time: 334 days in advance Interpretation: NX5948 achieved 69.2%; which is inferior to acalabrutinib's 80-85% ORR (see doi.org/10.1182/bloodadvances.2023011307)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to SoC BTK inhibitors) Classification: True Negative (TN)
1551	Belzupacap Sarotalocan (AU-011) NCTID: NCT05483868 Phase: Phase 1 Class: First-In-Class Modality: conjugate MoA: HPV nanoparticles conjugated with infrared-activated IR700 as a photodynamic therapy Area: Neoplasms Indication: Bladder Cancer Human Patients: 21 Sponsor: Aura Biosciences (AURA)	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/CR) Commercial: FAILURE (commercially insufficient clinical benefit for AU011 with inferior-to-pembrolizumab/tebentafusp-monootherapy efficacy in OS)	Readout: 17 Oct 2024 Lead Time: 180 days in advance Interpretation: Bel-sar achieved 50% CR (4/8); inferior to pembrolizumab's 100% CR at any time (ASCO 19 KEYNOTE-057)	Correct Prediction Conclusion: statistically significant and commercially insufficient (weak clinical benefit) Classification: True Negative (TN)
1374	AMX0035 NCTID: NCT05676034 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: sodium phenylbutyrate + taurursodiol Area: Nervous System Diseases / Genetic Diseases Indication: Wolfram Syndrome	Date: 13 Dec 2023 Quarter: Q1'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 17 Oct 2024 Lead Time: 309 days in advance Interpretation: AMX0035 achieved +36.7 min*ng/mL C-Peptide Response as the primary efficacy endpoint; and phase 2a safe and 100% participants meeting prespecified responding criteria (24 week -0.26% HbA1c; +7.6% target glucose range; +0.05 vision acuity;	Correct Prediction Conclusion: statistically probably significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 12 Sponsor: Amylyx Pharmaceuticals (AMLX)		62.5% CGIC and 75% PGIC).	
1742	WVE-006 NCTID: NCT06405633 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: base editing MoA: GalNAc-conjugated ADAR-dependent mRNA single-base modifier Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: alpha-1 antitrypsin deficiency (AATD) Human Patients: 24 Sponsor: Wave Life Sciences (WVE)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 5 Technical: SUCCESS (statistically significant additive clinical benefit in lung AAT/NE concentration) Commercial: SUCCESS (commercially sufficient additive clinical benefit in FEV1 superior to both fazirsiran and KB408)	Readout: 16 Oct 2024 Lead Time: 67 days in advance Interpretation: WVE-006 achieved 10.8 micromolar mean total AAT protein at day 15 (meeting the level that has been the basis for regulatory approval)	Correct Prediction Conclusion: statistically significant and commercially TBD (pending FEV1 data) Classification: True Positive (TP)
1748	Depemokimab (GSK3511294) NCTID: NCT05281523 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: ultra-long-acting anti-IL5 mAb inhibitor Area: Respiratory Tract Diseases Indication: Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) Human Patients: 264 Sponsor: GSK (GSK)	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant additive clinical benefit in NPS/SNOT22 against placebo) Commercial: SUCCESS (commercially sufficient additive clinical benefit in NPS/SNOT22 non-superior-non-inferior to tezepelumab)	Readout: 14 Oct 2024 Lead Time: 62 days in advance Interpretation: Depemokimab achieved the efficacy primary endpoint of total endoscopic nasal polyp score at week 52 and mean nasal obstruction score by week 52	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1747	Depemokimab (GSK3511294) NCTID: NCT05274750 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: ultra-long-acting anti-IL5 mAb inhibitor Area: Respiratory Tract Diseases Indication: Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) Human Patients: 276 Sponsor: GSK (GSK)	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant additive clinical benefit in NPS/SNOT22 against placebo) Commercial: SUCCESS (commercially sufficient additive clinical benefit in NPS/SNOT22 non-superior-non-inferior to tezepelumab)	Readout: 14 Oct 2024 Lead Time: 62 days in advance Interpretation: Depemokimab achieved the efficacy primary endpoint of total endoscopic nasal polyp score at week 52 and mean nasal obstruction score by week 52.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
477	VK0214 NCTID: NCT04973657 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: TRbeta agonist Area: Nervous System Diseases Indication: Adrenomyeloneuropathy Form (AMN) of X-linked Adrenoleukodystrophy (X-ALD) Human Patients: 36 Sponsor: Viking Therapeutics (VKTX)	Date: 12 Oct 2022 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 9 Oct 2024 Lead Time: 728 days in advance Interpretation: VK0214 achieved 37.9% placebo-adjusted VLCFA reduction at day 28 (p = 0.0105) and 24.9% placebo-adjusted LDL-C reduction at day 28 (p<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient (no FDA approved drug for X-ALD) Classification: True Positive (TP)
1382	SAGE-718 (dalzanemdor) NCTID: NCT05619692 Phase: Phase 2 Class: First-In-Class	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit)	Readout: 8 Oct 2024 Lead Time: 171 days in advance Interpretation: dalzanemdor failed to meet the primary efficacy endpoint.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule MoA: NMDAR PAM Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 174 Sponsor: Sage Therapeutics (SAGE)	Commercial: FAILURE (commercially insufficient clinical benefit)		Classification: True Negative (TN)
528	Apitegromab NCTID: NCT05156320 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: latent myostatin mAb inhibitor Area: Nervous System Diseases Indication: Spinal Muscular Atrophy (SMA) Human Patients: 188 Sponsor: Scholar Rock Holding (SRRK)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 3 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in HFMSE total score) Commercial: FAILURE (commercially insufficient additive clinical benefit in HFMSE total score non-superior to nusinersen/risdiplam monotherapy)	Readout: 7 Oct 2024 Lead Time: 62 days in advance Interpretation: apitegromab achieved 1.8 point HFMSE score difference at week 52 for the combined 10mg/kg and 20mg/kg populations (p=0.0192) yet only 1.4 point HFMSE score difference at week 52 for the 20mg/kg population (p=0.1149).	Correct Prediction Conclusion: statistically significant (yet weak benefit with negative dose-response relationship) and commercially insufficient (1.8 point is below the 3-point minimal threshold of clinically meaningful improvement in HFMSE score doi.org/10.1007/s40120-024-00653-2) Classification: True Negative (TN)
1627	Obinutuzumab NCTID: NCT04221477 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: type II anti-CD20 mAb inhibitor Area: Immune System Diseases Indication: Lupus Nephritis Human Patients: 252 Sponsor: Roche Group (RHHBY)	Date: 15 May 2024 Quarter: Q3'24 Batch 6 Technical: SUCCESS (statistically significant additive clinical benefit in CRR) Commercial: SUCCESS (commercially sufficient additive clinical benefit in eGFR)	Readout: 26 Sep 2024 Lead Time: 134 days in advance Interpretation: obinutuzumab achieved superiority over SoC alone in complete renal response at week 76 and in two other two secondary endpoints; yet eGFR secondary endpoint not met.	Overall Missed Prediction Note: due to suboptimal modelling of MoA with respect to the eGFR endpoint that has been materially impro... Conclusion: statistically significant and commercially maybe sufficient (FDA approved new medicine that hasn't demonstrated eGFR improvement in registrational trials) Classification: False Positive (FP)
1455	tavapadon NCTID: NCT04201093 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: a selective D1R/D5R partial agonist Area: Nervous System Diseases Indication: early Parkinson's Disease Human Patients: 522 Sponsor: AbbVie (ABBV)	Date: 14 Feb 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially insufficient additive clinical benefit superior to levodopa for patients who receive tavapadon + MAOB inhibitor combination therapy); partial FAILURE (commercially insufficient clinical benefit non-superior to levodopa for patients who receive tavapadon monotherapy)	Readout: 26 Sep 2024 Lead Time: 225 days in advance Interpretation: tavapadon achieved -11.5 to -12 improvement (p< 0.0001) in MDS-UPDRS Parts II and III combined score at week 26; numerically slightly superior to -10.8 improvement in MDS-UPDRS total score achieved by Levodopa at week 26 (doi/full/10.1056/NEJMoa033447); thus commercially insufficient because levodopa is a generic.	Overall Correct Prediction Conclusion: statistically significant and commercially probably insufficient as monotherapy (combination therapy data TBD) Classification: True Negative (TN)
1782	Patritumab Deruxtecan NCTID: NCT05338970 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-HER3 ADC conjugated with a TOP1 inhibitor payload Area: Neoplasms Indication: advanced NSCLC Human Patients: 586 Sponsor: Daiichi Sankyo Company / Merck & Co. (DSNKY/MRK)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS numerically superior to chemotherapy yet numerically inferior to BL-B01D1); partial FAILURE (statistically insignificant clinical benefit in tolerability inferior to chemotherapy yet numerically superior to BL-B01D1) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to chemotherapy yet numerically superior to BL-B01D1)	Readout: 24 Sep 2024 Lead Time: 15 days in advance Interpretation: statistically significant improvement in PFS over the SoC chemotherapy (without disclosure of the specific data and p-value; indicating probably weak efficacy in PFS).	Correct Prediction Conclusion: statistically probably weakly significant (in PFS) and commercially TBD (OS data not mature) Classification: True Negative (TN)
1595	WVE-N531 NCTID: NCT04906460	Date: 12 May 2024 Quarter: Q3'24 Batch 6	Readout: 24 Sep 2024 Lead Time: 135 days in advance	Correct Prediction Note: Correct Technical prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: siRNA MoA: stereopure exon 53 skipping antisense oligonucleotides Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 11 Sponsor: Wave Life Sciences (WVE)	Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin protein level) partial FAILURE (statistically insignificant clinical benefit in NSAA/10MRW/SV95C) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD non-superior and non-inferior to DYNE251 or SRP5051)	Interpretation: a mean absolute dystrophin expression of 5.5%; which is relatively higher than competitor drugs.	(commercial data TBD) Conclusion: statistically partially significant (dystrophin expression) and partially TBD (functional endpoints) and commercially TBD Classification: True Positive (TP)
1446	Inebilizumab NCTID: NCT04524273 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD19 mAb inhibitor Area: Immune System Diseases Indication: generalized myasthenia gravis (gMG) Human Patients: 238 Sponsor: Amgen (AMGN)	Date: 5 Feb 2024 Quarter: Q3'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 24 Sep 2024 Lead Time: 232 days in advance Interpretation: inebilizumab achieved 1.9 placebo-adjusted MG-ADL score reduction at week 26 (p < 0.0001); numerically superior to efgartigimod's 1.6-1.7 placebo-adjusted MG-ADL score reduction at week 8-11 (doi: 10.1212/WNL.0000000000007600); commercially sufficient for unsaturated market.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1445	Rocatinlimab NCTID: NCT05651711 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-OX40 mAb inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis Human Patients: 726 Sponsor: Amgen (AMGN)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in EASI75; superior to dupilumab/lebrikizumab; non-superior-and-non-inferior to amltelimab; yet inferior to upadacitinib)	Readout: 24 Sep 2024 Lead Time: 45 days in advance Interpretation: rocatinlimab achieved 19.1% placebo-adjusted EASI75 at week 24; inferior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see 10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see 10.1016/S0140-6736(21)00588-2).	Overall Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: True Positive (TP)
1602	BDTX1535 NCTID: NCT05256290 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: 4th-gen CNS-penetrant EGFR masterkey inhibitor that targets classical; non-classical; and resistance EGFR mutations Area: Neoplasms Indication: advanced EGFRm-NSCLC Human Patients: 200 Sponsor: Black Diamond Therapeutics (BDTX)	Date: 12 May 2024 Quarter: Q3'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS with non-superior-to-osimertinib efficacy in the clinical setting of 1L EGFR-mutant NSCLC and non-superior-to-chemotherapy efficacy in the clinical setting of 2L EGFR-C797S-mutation NSCLC)	Readout: 23 Sep 2024 Lead Time: 134 days in advance Interpretation: 23% cORR (5/22) and 36% overall ORR (8/22); significantly better than placebo.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD (OS data not available) Classification: True Positive (TP)
1682	INV-202 (Monlunabant) NCTID: NCT05891834 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: peripherally selective beta-arrestin-2-biased CB1 inverse agonist Area: Nutritional and Metabolic Diseases Indication: Obesity and Metabolic Syndrome Human Patients: 243 Sponsor: Novo Nordisk (NVO)	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically significant yet weak clinical benefit in weight reduction against placebo with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in weight reduction and adverse effect both inferior to semaglutide)	Readout: 20 Sep 2024 Lead Time: 65 days in advance Interpretation: monlunabant achieved 5.8% placebo-adjusted weight reduction in week 16; inferior to tirzepatide 9% placebo-adjusted weight reduction in week 16 (see 10.1056/NEJMoa2206038); Reporting mild-to-moderate psychiatric side effects in addition to typical GI adverse effects.	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to tirzepatide in both efficacy and toxicity) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
1601	EDG-7500 NCTID: NCT06347159 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: oral selective cardiac sarcomere modulator Area: Cardiovascular Diseases Indication: Hypertrophic Cardiomyopathy (HCM) Human Patients: 55 Sponsor: Edgewise Therapeutics (EWTX)	Date: 12 May 2024 Quarter: Q3'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in LVOT-G) Commercial: SUCCESS (commercially sufficient clinical benefit with maybe-superior to-CK274 and superior-to-metoprolol-succinate efficacy in LVOT-G)	Readout: 19 Sep 2024 Lead Time: 130 days in advance Interpretation: EDG7500 achieved 67% mean reduction in resting LVOT-G and 55% mean reduction in provokable LVOT-G at day 10; which are superior to aficamten's 44.8% mean reduction in provokable LVOT-G at week 12 (DOI-10.1056/NEJMoa2401424)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1734	BTN211-01 NCTID: NCT04503278 Phase: Phase 1 Class: First-In-Class Modality: CAR-T MoA: anti-CLDN6 CAR-T cell and CLDN6 mRNA vaccine Area: Neoplasms Indication: Advanced solid tumors Human Patients: 145 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS as monotherapy or in combination with CLDN6 mRNA vaccine) Commercial: FAILURE (commercially insufficient clinical benefit in OS as monotherapy or in combination with CLDN6 mRNA vaccine)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BTN211-01 with/without CARVac achieved 5% real ORR (not counting tumor marker responses; there were 3/64 patients who achieved PR or CR) in testicular/ovarian cancer; very low efficacy.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically maybe significant (against placebo) and commercially TBD Classification: True Negative (TN)
1732	BNT327/PM8002 NCTID: NCT05918445 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-PDL1 and anti-VEGF bsAb Area: Neoplasms Indication: advanced RCC Human Patients: 380 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to pembrolizumab + lenvatinib)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT327 achieved 25% cORR + 10.9-month mPFS as 2L for ccRCC; which is non-superior to 43% ORR + 14.6-month mPFS achieved by Lenvatinib + Everolimus (Lancet doi-10.1016/S1470-2045(15)00290-9) and BNT327 achieved 36% cORR + 15.1-month mPFS as 1L for nccRCC; which is non-superior to 49% ORR + 17.9-month mPFS achieved by pembrolizumab + lenvatinib in KEYNOTE-B61 study (Lancet DOI-10.1016/S1470-2045(23)00276-0).	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant (against placebo) and commercially TBD Classification: True Positive (TP)
1733	BNT113 NCTID: NCT04534205 Phase: Phase 2 Class: First-In-Class Modality: mRNA vaccine MoA: HPV16 E6/7 RNA-LPX mRNA vaccine Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 285 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS against pembrolizumab) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to pembrolizumab + chemotherapy as 1L SoC)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT113 + pembrolizumab achieved 40% uORR + 3.9-month mPFS; which is non-superior to 36% ORR + 4.9-month mPFS achieved by chemo + pembrolizumab in KEYNOTE-048 (Lancet DOI-10.1016/S0140-6736(19)32591-7).	Correct Prediction Conclusion: statistically maybe significant (yet weak additive efficacy) and commercially TBD Classification: True Negative (TN)
1731	BNT327/PM8002 NCTID: NCT05756972 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PDL1 and anti-VEGF bsAb Area: Neoplasms Indication: Non-Small-Cell Lung Cancer Human Patients: 374 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS non-superior to carboplatin + pemetrexed combotherapy) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to carboplatin + pemetrexed combotherapy)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT327 + chemotherapy achieved 37% cORR; numerically superior to 29% cORR achieved by chemotherapy alone; BNT327 + chemotherapy achieved 61% Grade 3 TEAE; inferior to 20-40% Grade 3 TEAE achieved by chemotherapy alone (see 10.1177/1758834016644155).	Correct Prediction Conclusion: statistically maybe significant (slightly higher ORR with inferior tolerability) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1607	PBFT02 NCTID: NCT04747431 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV1-mediated GRN gene therapy Area: Nervous System Diseases Indication: Frontotemporal Dementia and Progranulin Mutations (FTD-GRN) Human Patients: 15 Sponsor: Passage Bio (PASG)	Date: 13 May 2024 Quarter: Q3'24 Batch 8 Technical: partial SUCCESS (statistically significant yet weak clinical benefit in CDR + NACC FTLD) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in CDR + NACC FTLD)	Readout: 16 Sep 2024 Lead Time: 126 days in advance Interpretation: PBFT02 increased CSF PGRN expression up to 6-10 fold exceeding the range found in healthy adult controls; yet plasma PGRN expression remained below healthy reference levels.	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
660	TransCon CNP NCTID: NCT05598320 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: peptide prodrug MoA: long-lasting c-type natriuretic peptide Area: Musculoskeletal Diseases Indication: Achondroplasia Human Patients: 84 Sponsor: Ascendis Pharma (ASND)	Date: 29 Aug 2024 Quarter: Q4'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit in AGV against placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in AGV inferior to vosoritide due to suboptimal dosage)	Readout: 16 Sep 2024 Lead Time: 18 days in advance Interpretation: once-weekly TransCon CNP achieved an AGV with LS mean treatment difference 1.49 cm/year; which is lower than 1.57cm/year achieved by the once-daily SoC vosoritide.	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (weaker efficacy yet better adherence with once-weekly administration) Classification: True Positive (TP)
1784	BT8009 NCTID: NCT04561362 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bicycle toxin conjugate MoA: anti-nectin4 BTC with MMAE payload Area: Neoplasms Indication: metastatic urothelial cancer Human Patients: 329 Sponsor: Bicycle Therapeutics (BCYC)	Date: 12 Sep 2024 Quarter: Q4'24 Batch 17a Technical: partial SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS numerically inferior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS non-inferior-non-superior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors that don't have FDA-approved drugs)	Readout: 14 Sep 2024 Lead Time: 2 days in advance Interpretation: BT8009 achieved 36.8% cORR (14/38); lower than enfortumab vedotin 40.6% cORR (NEJM DOI-10.1056/NEJMoa2035807).	Correct Prediction Conclusion: statistically significant (numerically inferior to enfortumab vedotin) and commercially TBD Classification: True Positive (TP)
1778	INCB123667 NCTID: NCT05238922 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: CDK2 inhibitor Area: Neoplasms Indication: Solid Tumors Human Patients: 340 Sponsor: Incyte Corporation (INCY)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 14 Sep 2024 Lead Time: 5 days in advance Interpretation: INCB123667 achieved 24.3% ORR (<25% is generally accepted as weak efficacy) without positive dose-response relationship.	Overall Correct Prediction Conclusion: statistically maybe significant (yet weak efficacy) and commercially TBD Classification: True Negative (TN)
1416	ponsegromab NCTID: NCT05546476 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-GDF15 mAb inhibitor Area: Neoplasms Indication: Cancer Cachexia Human Patients: 187 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Sep 2024 Lead Time: 243 days in advance Interpretation: ponsegromab exhibited non-positive dose-response relationship and failed to meet key secondary/exploratory endpoints (at most 4-point increase in FAACT-ACS; at most 2-point increase in FAACT-5IASS; CRCSD; physical activity; gait endpoints).	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
661	TransCon IL-2^{2/3} Pembrolizumab Chemotherapy drug TransCon TLR7/8 Agonist Surgery NCTID: NCT05081609 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: protein prodrug MoA: IL-2^{2/3} agonist Area: Neoplasms Indication: Solid Tumor Malignancies Human Patients: 473 Sponsor: Ascendis Pharma (ASND)	Date: 29 Aug 2024 Quarter: Q4'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit for TransCon IL2 for certain cancer subindications only); partial FAILURE (statistically insignificant clinical benefit for TransCon TLR7/8) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit for TransCon IL2 for certain cancer subindications only); partial FAILURE (commercially insufficient clinical benefit for TransCon TLR7/8)	Readout: 13 Sep 2024 Lead Time: 15 days in advance Interpretation: TransCon chemotherapy achieved 11% cORR for PROC (2/18 including 4 discontinued patients); much lower than targeted therapy mirvetuximab soravtansine (32.4% ORR for FRalpha-expressing PROC).	Overall Correct Prediction Conclusion: statistically probably insignificant (very weak efficacy) and commercially TBD Classification: True Negative (TN)
1364	Luvadaxistat NCTID: NCT05182476 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: DAAO inhibitor Area: Nervous System Diseases Indication: Schizophrenia Human Patients: 216 Sponsor: Neurocrine Biosciences (NBIX)	Date: 30 Nov 2023 Quarter: Q3'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Sep 2024 Lead Time: 287 days in advance Interpretation: uvadaxistat failed to meet primary endpoint.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1594	SER-155 NCTID: NCT04995653 Phase: Phase 1 Class: First-In-Class Modality: microbiome therapeutic MoA: oral 16-strain cultivated microbiome therapeutic Area: Immune System Diseases Indication: Graft vs. Host Disease (GvHD) Human Patients: 60 Sponsor: Seres Therapeutics (MCRB)	Date: 12 May 2024 Quarter: Q3'24 Batch 6 Technical: SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-steroid-or-ruxolitinib efficacy)	Readout: 12 Sep 2024 Lead Time: 123 days in advance Interpretation: SER155 achieved a lower-than-placebo incidence of bacterial bloodstream infections (BSIs) (10% vs 42.9% p=0.0423) yet insignificant incidence of febrile neutropenia (p=0.4674).	Correct Prediction Conclusion: statistically borderline significant and commercially insufficient (weak efficacy) Classification: True Negative (TN)
1629	Losmapimod NCTID: NCT05397470 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: p38$\pm$/γ-MAPKs small molecule inhibitor Area: Musculoskeletal Diseases Indication: Facioscapulohumeral Muscular Dystrophy (FSHD) Human Patients: 260 Sponsor: Fulcrum Therapeutics (FULC)	Date: 25 Jul 2024 Quarter: Q4'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in RWS) Commercial: FAILURE (commercially insufficient clinical benefit in RWS for patients that are not stratified by p38MAPK expression levels)	Readout: 12 Sep 2024 Lead Time: 49 days in advance Interpretation: losmapimod failed to meet RWS primary endpoint.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1740	dupilumab NCTID: NCT04180488 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-IL4 and anti-IL13 mAb inhibitor Area: Immune System Diseases Indication: chronic spontaneous urticaria (CSU) Human Patients: 397	Date: 10 Aug 2024 Quarter: Q4'24 Batch 5 Technical: SUCCESS (statistically significant yet moderate clinical benefit in ISS7/UAS7 against placebo in biologic-naïve refractory CSU patients) Commercial: FAILURE (commercially insufficient clinical benefit in ISS7/UAS7 inferior to both omalizumab and barzolvolimab in	Readout: 10 Sep 2024 Lead Time: 31 days in advance Interpretation: dupilumab achieved 12% placebo-adjusted CR at week 24 (p=0.02) vs. 31% placebo-adjusted CR at week 12 achieved by barzolvolimab in NCT05368285 vs 27% placebo-adjusted CR at week 12 achieved by omalizumab in ASTERIA I study.	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to both omalizumab and barzolvolimab) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Sanofi (SNY)	biologic-naïve refractory CSU patients)		
1247	NVL-655 NCTID: NCT05384626 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: CNS-penetrant mutant-selective ALK inhibitor Area: Neoplasms Indication: Advanced NSCLC and Other Solid Tumors Human Patients: 400 Sponsor: Nuvalent (NUVL)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 11 Technical: partial SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo for all cohorts; non-superior to lorlatinib/alectinib for cohort 2c/2d/2e/2f) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in OS without mutation-specific stratification; superior to lorlatinib for cohort 2a/2b/2c/2d/2e/2f; non-superior to alectinib for cohort 2c/2d/2e/2f)	Readout: 9 Sep 2024 Lead Time: 25 days in advance Interpretation: NVL655 achieved 38% confirmed ORR vs. 48% confirmed ORR achieved by lorlatinib in NCT01970865.	Correct Prediction Conclusion: statistically significant (against placebo non-superior to lorlatinib) and commercially TBD Classification: True Positive (TP)
975	RLY-2608 NCTID: NCT05216432 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: pan-mutant-selective (H1047X; E542X; and E535X) PI3Kalpha inhibitor Area: Neoplasms Indication: Advanced Breast Cancer Human Patients: 400 Sponsor: Relay Therapeutics (RLAY)	Date: 11 Jul 2024 Quarter: Q3'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in ORR/PFS non-superior to alpelisib; in combination with fulvestrant and/or palbociclib/ribociclib) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS inferior to alpelisib; in combination with fulvestrant and/or palbociclib/ribociclib)	Readout: 9 Sep 2024 Lead Time: 60 days in advance Interpretation: RLY2608 + fulvestrant achieved 30% confirmed ORR and 9.2months mPFS vs. 26.6% confirmed ORR and 11months mPFS achieved by alpelisib + fulvestrant.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant (ORR/PFS non-superior to alpelisib + fulvestrant) and commercially TBD Classification: True Positive (TP)
1698	TERN-601 NCTID: N/A (adapt NCT05762471 as reference) Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: oral small molecule GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 37 Sponsor: Terns Pharmaceuticals (TERN)	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: SUCCESS (statistically significant clinical benefit in weight reduction against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in weight reduction inferior to VK2735; non-superior non-inferior to orforglipron/GSBR1290)	Readout: 9 Sep 2024 Lead Time: 47 days in advance Interpretation: TERN601 achieved 4.9% placebo-adjusted weight reduction at week 4 (N=9) vs. 3.2% placebo-adjusted weight reduction at week 4 achieved by orforglipron (N=57).	Correct Prediction Conclusion: statistically significant (placebo) and commercially sufficient (non-superior non-inferior to orforglipron) Classification: True Positive (TP)
1470	Dapiglutide NCTID: NCT05788601 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: peptide MoA: dual GLP1R/GLP2R agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 54 Sponsor: Zealand Pharma (ZEAL.CO)	Date: 15 Feb 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to tirzepatide)	Readout: 9 Sep 2024 Lead Time: 207 days in advance Interpretation: dapiglutide achieved 8.9% placebo-adjusted weight reduction at week 13 vs. 7% placebo-adjusted weight reduction at week 13 achieved by tirzepatide.	Correct Prediction Conclusion: statistically significant and commercially sufficient (superior to tirzepatide) Classification: True Positive (TP)
1666	Ivonescimab (AK112) NCTID: NCT05499390 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-1 and anti-VEGF	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS superior to pembrolizumab)	Readout: 8 Sep 2024 Lead Time: 61 days in advance Interpretation: Median PFS of 11.14 Months vs. 5.82 Months by pembrolizumab and serious TRAEs were 20.8% vs. 16.1%; respectively;	Correct Prediction Conclusion: statistically significant and commercially sufficient (superior) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	tetravalent bsAb Area: Neoplasms Indication: Advanced Non-small-cell Lung Cancer Human Patients: 398 Sponsor: Summit Therapeutics (SMMT)	Commercial: SUCCESS (commercially sufficient clinical benefit in OS superior to pembrolizumab)	in ivonescimab and pembrolizumab arms.	
1749	mepolizumab NCTID: NCT04133909 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-IL5 mAb inhibitor Area: Respiratory Tract Diseases Indication: Chronic Obstructive Pulmonary Disease (COPD) Human Patients: 806 Sponsor: GSK (GSK)	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit in exacerbation ratio) Commercial: FAILURE (commercially insufficient additive clinical benefit in exacerbation ratio)	Readout: 6 Sep 2024 Lead Time: 24 days in advance Interpretation: primary endpoint of annualized exacerbation reduction was met with statistically significant and clinically meaningful efficacy.	Missed Prediction Note: due to suboptimal modelling of eosinophil count in the clinical setting of COPD. Conclusion: statistically significant and commercially sufficient Classification: False Negative (FN)
720	Insulin Efsitora Alfa (LY3209590) Insulin Degludec NCTID: NCT05275400 Phase: Phase 3 Class: Best-In-Class Modality: protein biologic MoA: once-weekly insulin treatment Area: Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Human Patients: 986 Sponsor: Eli Lilly and Company (LLY)	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS (non-inferior) Commercial: SUCCESS (non-inferior)	Readout: 5 Sep 2024 Lead Time: 649 days in advance Interpretation: -0.86% (efsitora) vs -0.76% (degludec) HbA1C at week 26.	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferior) Classification: True Positive (TP)
1628	fosgonimeton (ATH-1017) NCTID: NCT04488419 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: HGF/MET agonist Area: Nervous System Diseases Indication: Alzheimer's Disease Human Patients: 554 Sponsor: Athira Pharma (ATHA)	Date: 24 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to lecanemab)	Readout: 3 Sep 2024 Lead Time: 71 days in advance Interpretation: none of the primary and secondary endpoints were met; with numerical treatment effect for APOE4 carriers.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1253	DYNE-251 NCTID: NCT05524883 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: siRNA MoA: dystrophin exon 51 skipping Fab Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 88 Sponsor: Dyne Therapeutics (DYN)	Date: 21 Nov 2023 Quarter: Q1'24 Batch 7 Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin protein level); partial FAILURE (statistically insignificant clinical benefit in NSAA/10MRW/FVC) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD)	Readout: 3 Sep 2024 Lead Time: 287 days in advance Interpretation: a mean absolute dystrophin expression of 3.71% of normal; yet weak functional efficacy(change from baseline in SV95C only meet EMA-defined minimal clinically important difference (MCID); whereas other functional efficacy endpoints NSAA/10MWR probably didn't reach MCID).	Overall Correct Prediction Conclusion: statistically partially significant (dystrophin expression) and partially insignificant (functional endpoints) and commercially probably insufficient (weak efficacy) Classification: True Negative (TN)
1244	PRAX-562 NCTID: NCT05818553 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: anti-SCN8A antagonist Area: Nervous System Diseases Indication: Developmental and	Date: 5 Jan 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit more for SCN8A-mutant patients than for SCN2A-mutant patients) Commercial: SUCCESS	Readout: 3 Sep 2024 Lead Time: 242 days in advance Interpretation: 46% placebo-adjusted reduction in monthly motor seizure and thus primary endpoint met (whether efficacy is better for SCN8A-DEE is pending for further data).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Epileptic Encephalopathies Human Patients: 20 Sponsor: Praxis Precision Medicines (PRAX)	(commercially sufficient clinical benefit for SCN8A-mutant patients)		
1428	Tolebrutinib NCTID: NCT04410991 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant BTK inhibitor Area: Nervous System Diseases Indication: Relapsing Forms of Multiple Sclerosis (RMS) Human Patients: 899 Sponsor: Sanofi (SNY)	Date: 24 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to teriflunomide)	Readout: 2 Sep 2024 Lead Time: 222 days in advance Interpretation: superiority primary endpoint (Tolebrutinib vs teriflunomide in annualized relapse rate reduction) not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1427	Tolebrutinib NCTID: NCT04410978 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CNS-penetrant BTK inhibitor Area: Nervous System Diseases Indication: Relapsing Forms of Multiple Sclerosis (RMS) Human Patients: 974 Sponsor: Sanofi (SNY)	Date: 24 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to teriflunomide)	Readout: 2 Sep 2024 Lead Time: 222 days in advance Interpretation: superiority primary endpoint (Tolebrutinib vs teriflunomide in annualized relapse rate reduction) not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1377	Vutrisiran Sterile Normal Saline (0.9% NaCl) NCTID: NCT04153149 Phase: Phase 3 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: anti-TTR siRNA Area: Nutritional and Metabolic Diseases Indication: Transthyretin Amyloidosis (ATTR) With Cardiomyopathy Human Patients: 655 Sponsor: Alnylam Pharmaceuticals (ALNY)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 11 Technical: FAILURE (statistically maybe significant yet weak clinical benefit for the composite endpoint) Commercial: FAILURE (commercially insufficient clinical benefit inferior to both tafamidis and acoramidis)	Readout: 30 Aug 2024 Lead Time: 252 days in advance Interpretation: composite primary endpoint met (1.2% ARR and 13.8% RRR at month 30); inferior to 6.4% ARR and 25% RRR at month 30 p<0.0001 for Acoramidis in ATTRIBUTE-cm study; and inferior to 13.4% ARR and 31.2% RRR at month 30 p=0.0006 for tafamidis in ATTR-ACT study); secondary endpoint 6MWD met p<0.025 (vs p<0.0001 for both Acoramidis and tafamidis); all cause mortality met with p<0.05.	Correct Prediction Conclusion: statistically significant and commercially insufficient inferior to both Acoramidis and tafamidis Classification: True Negative (TN)
1661	NBI-1117568 NCTID: NCT05545111 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral CHRM4 agonist Area: Nervous System Diseases Indication: Schizophrenia Human Patients: 213 Sponsor: Neurocrine Biosciences (NBIX)	Date: 6 Jul 2024 Quarter: Q3'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PANSS at week 6 against placebo featuring moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in PANSS and toxicity inferior to KarXT yet non-inferior/non-superior to emraclidine)	Readout: 28 Aug 2024 Lead Time: 53 days in advance Interpretation: achieved 7.5 point placebo-adjusted improvement in PNASS score; inferior to the SoC KarXT that showed 11.6-point placebo-adjusted improvement in phase 3 studies.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1304	Cabozantinib NCTID: NCT03937219 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: RTK inhibitor	Date: 31 Oct 2023 Quarter: Q1'24 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially	Readout: 24 Aug 2024 Lead Time: 298 days in advance Interpretation: cabozantinib failed to achieve additive clinical benefit in OS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: Renal Cell Carcinoma Human Patients: 855 Sponsor: Exelixis (EXEL)	insufficient clinical benefit)		
1358	Tafasitamab Rituximab Lenalidomide Placebo NCTID: NCT04680052 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD19 Fc-enhanced mAb Area: Neoplasms Indication: Relapsed / (R / R) Follicular Lymph Marginal Zone Lymphoma Human Patients: 654 Sponsor: Incyte Corporation (INCY)	Date: 30 Nov 2023 Quarter: Q3'24 Batch 16 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 15 Aug 2024 Lead Time: 259 days in advance Interpretation: superior to the SoC (Lenalidomide + Rituximab) for both PFS (primary endpoint met) and and CR (secondary endpoint met).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1560	TBio-4101 Pembrolizumab NCTID: NCT05576077 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: autologous TIL cell therapy Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 60 Sponsor: Turnstone Biologics (TSBX)	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 14 Aug 2024 Lead Time: 113 days in advance Interpretation: 25% ORR achieved by TBio-4101 + pembrolizumab for MSI-stable CRC vs 30%-40% ORR achieved by regorafenib+ novolumab (Fakih et al. Huyck 2023 eClinicalMedicine).	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)
1535	LTX-315 Part 1 VP-315 Part 2 NCTID: NCT05188729 Phase: Phase 2 Class: First-In-Class Modality: oncolytic peptide therapy MoA: oncolytic peptide immunotherapy derived from bovine lactoferrin Area: Neoplasms Indication: Basal Cell Carcinoma Human Patients: 80 Sponsor: Verrica Pharmaceuticals (VRCA)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit in clinical clearance) Commercial: FAILURE (commercially insufficient clinical benefit inferior to imiquimod)	Readout: 14 Aug 2024 Lead Time: 127 days in advance Interpretation: 51% CR lower than 80% CR achieved by imiquimod (DOI- 10.1016/j.jaad.2003.11.066).	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to imiquimod) Classification: True Negative (TN)
1743	KZR-261 NCTID: NCT05047536 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: small molecule SEC61 inhibitor Area: Neoplasms Indication: Advanced Solid Malignancies Human Patients: 61 Sponsor: Kezar Life Sciences (KZR)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 13 Aug 2024 Lead Time: 3 days in advance Interpretation: 0% ORR and trial terminated	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1188	Izokibep NCTID: NCT05905783 Phase: Phase 3 Class: Best-In-Class Modality: small protein	Date: 22 Jul 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant)	Readout: 12 Aug 2024 Lead Time: 387 days in advance Interpretation: izokibep achieved 14% placebo-adjusted HiSCR100; superior to single-digit placebo-adjusted	Overall Correct Prediction Conclusion: statistically significant and commercially fairly sufficient (superior to adalimumab and non-inferior to sonelokimab)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	scaffold-based biologic MoA: IL-17A Inhibitor Area: Immune System Diseases Indication: Hidradenitis Suppurativa Human Patients: 258 Sponsor: Acelyrin (SLRN)	Commercial: SUCCESS (commercially sufficient clinical benefit superior to adalimumab and non-inferior to sonelokimab)	HiSCR100 achieved by adalimumab; and above the inferior threshold compared with 20%-30% placebo-adjusted HiSCR100 achieved by sonelokimab.	Classification: True Positive (TP)
1183	Izokibep NCTID: NCT05355805 Phase: Phase 2 Class: First-In-Class Modality: small protein scaffold-based biologic MoA: IL-17A Inhibitor Area: Immune System Diseases Indication: Hidradenitis Suppurativa Human Patients: 176 Sponsor: Acelyrin (SLRN)	Date: 22 Jul 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant) Commercial: SUCCESS (commercially sufficient clinical benefit superior to adalimumab and non-inferior to sonelokimab)	Readout: 12 Aug 2024 Lead Time: 387 days in advance Interpretation: izokibep achieved 14% placebo-adjusted HiSCR100; superior to single-digit placebo-adjusted HiSCR100 achieved by adalimumab; and above the inferior threshold compared with 20%-30% placebo-adjusted HiSCR100 achieved by sonelokimab.	Overall Correct Prediction Conclusion: statistically significant and commercially fairly sufficient (superior to adalimumab and non-inferior to sonelokimab) Classification: True Positive (TP)
1625	Tamibarotene Venetoclax Azacitidine NCTID: NCT04905407 Phase: Phase 2 Class: First-In-Class Modality: synthetic retinoid MoA: RARalpha agonist Area: Neoplasms Indication: Acute Myeloid Leukemia Human Patients: 95 Sponsor: Syros Pharmaceuticals (SYRS)	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: FAILURE (statistically insignificant additive clinical benefit in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	Readout: 12 Aug 2024 Lead Time: 89 days in advance Interpretation: CR/CRi achieved by tamibarotene + SoC vs 70% CR/CRi achieved by SoC; and trial terminated.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1695	Epetraborole NCTID: NCT05327803 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: a novel bacterial leucyl-tRNA synthetase inhibitor Area: Respiratory Tract Diseases Indication: MAC Lung Disease Human Patients: 314 Sponsor: AN2 Therapeutics (ANTX)	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: FAILURE (statistically insignificant additive clinical benefit in clinical response as an adjunctive therapy to SoC) Commercial: FAILURE (commercially insufficient additive clinical benefit in reinfection/relapse as an adjunctive therapy to SoC)	Readout: 8 Aug 2024 Lead Time: 15 days in advance Interpretation: 13.9% placebo-adjusted difference (p=0.19) in PRO-based clinical response rate and trial discontinued for low efficacy.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
882	Pegcetacoplan NCTID: NCT05067127 Phase: Phase 3 Class: First-In-Class Modality: PEGylated peptide MoA: PEGylated C3b inhibitor Area: Urogenital Diseases Indication: C3 glomerulopathy (C3G) or immune-complex membranoproliferative glomerulonephritis (IC-MPGN) Human Patients: 90 Sponsor: Apellis Pharmaceuticals (APLS)	Date: 14 May 2024 Quarter: Q3'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit in eGFR)	Readout: 8 Aug 2024 Lead Time: 86 days in advance Interpretation: Pegcetacoplan achieved 68% placebo-adjusted reduction in proteinuria (p<0.0001) and statistically significant improvement in eGFR secondary endpoint.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1554	EO-3021 NCTID: NCT05980416 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit due to	Readout: 6 Aug 2024 Lead Time: 105 days in advance Interpretation: EO-3021 achieved 20% ORR which is significantly lower than 47% ORR achieved by EO-3021	Overall Correct Prediction Conclusion: statistically significant (moderate ORR) and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	conjugate (ADC) MoA: DAR-2 anti-claudin18.2 ADC with MMAE as payload Area: Neoplasms Indication: Pancreas Neoplasm Stomach Neoplasm Gastrointestinal Neoplasms Digestive System Neoplasm Neoplasms by Site Neoplasms Human Patients: 120 Sponsor: Elevation Oncology (ELEV)	dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit with non-superior-to-zolbetuximab efficacy and non-superior-to-zolbetuximab toxicity)	in previous Chinese-only study; 42.8% ORR for CLDN18.2 > 20% and 0% ORR for Claudin 18.2 <20% Four dose-limiting toxicities at 2.9mg/kg dose.	Classification: True Negative (TN)
1095	Evorpacept (ALX148) NCTID: NCT05002127 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: fusion protein biologic MoA: anti-CD47 blocker Area: Neoplasms Indication: Advanced HER2+ Gastric Cancer Human Patients: 450 Sponsor: ALX Oncology (ALXO)	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: SUCCESS (statistically significant additive clinical benefit to trastuzumab + ramucirumab + paclitaxel in ORR as 2L/3L treatments for advanced HER2-overexpressing gastric cancer for phase 2) Commercial: SUCCESS (statistically significant additive clinical benefit to trastuzumab + ramucirumab + paclitaxel in OS as 2L/3L treatments for advanced HER2-overexpressing gastric cancer for phase 3)	Readout: 31 Jul 2024 Lead Time: 36 days in advance Interpretation: evorpacept+TRP achieved an ORR of 40.3% vs 26.6% achieved by TRP (a 13.7% delta which is lower than 30% delta at interim).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1677	Biological- Human Acellular Vessel (HAV) Procedure-Arteriovenous fistula (AVF) NCTID: NCT03183245 Phase: Phase 3 Class: First-In-Class Modality: bioengineered acellular tissue (Device) MoA: tissue-engineer acellular vascular conduit Area: Renal Replacement Therapy Indication: Hemodialysis Human Patients: 240 Sponsor: Humacyte (HUMA)	Date: 14 Jul 2024 Quarter: Q3'24 Batch 17 Technical: SUCCESS (statistically significant clinical benefit in proportion of subjects with functional patency at month 6 non-inferior to AVF and proportion of subjects with secondary patency at month 12 superior to AVF) Commercial: SUCCESS (commercially sufficient clinical benefit in patency/infection/aneurysm increasingly superior to AVF as time progresses)	Readout: 31 Jul 2024 Lead Time: 17 days in advance Interpretation: functional patency at month 6 and secondary patency at month 12 jointly superior to SoC AV fistula (p=0.0071).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1557	PGN-EDO51 NCTID: NCT06079736 Phase: Phase 2 Class: First-In-Class Modality: peptide-conjugated antisense oligonucleotide ASO MoA: EDO cell-penetrating peptide conjugated with dystrophin exon 51 skipping oligonucleotide Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 10 Sponsor: PepGen (PEPG)	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in dystrophin protein level) Commercial: FAILURE (commercially insufficient clinical benefit in the registrational endpoint 6MWD non-superior-to and non-inferior-to SRP-5051)	Readout: 30 Jul 2024 Lead Time: 98 days in advance Interpretation: 5mg low-dose exon skipping level and dystrophin level comparable to SRP5051 20mg (NCT04004065).	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD (pending functional efficacy data) Classification: True Positive (TP)
456	Pamrevlumab + Gemcitabine + Nab-paclitaxel or Pamrevlumab + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX NCTID: NCT03941093 Phase: Phase 3 Class: First-In-Class	Date: 15 May 2024 Quarter: Q3'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant additive clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 30 Jul 2024 Lead Time: 76 days in advance Interpretation: OS endpoint not met (p=0.55).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: monoclonal antibody MoA: anti-CTGF mAb inhibitor Area: Neoplasms Indication: Locally Advanced Pancreatic Cancer Human Patients: 284 Sponsor: FibroGen (FGEN)			
861	Barzolvolimab Matching Placebo NCTID: NCT05405660 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: KIT receptor tyrosine kinase inhibitor Area: Skin and Connective Tissue Diseases Indication: Chronic Inducible Urticaria Human Patients: 196 Sponsor: Celldex Therapeutics (CLDX)	Date: 19 Aug 2023 Quarter: 2H'23 Batch 16 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 29 Jul 2024 Lead Time: 345 days in advance Interpretation: CDX0159 achieved 40.6% placebo-adjusted CR.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1257	VTX958 NCTID: NCT05688852 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral selective allosteric TYK2 inhibitor Area: Immune System Diseases Indication: Crohn Disease Human Patients: 132 Sponsor: Ventyx Biosciences (VTYX)	Date: 23 Apr 2024 Quarter: Q3'24 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 29 Jul 2024 Lead Time: 97 days in advance Interpretation: primary endpoint in CDAI score not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1011	Obicetrapib NCTID: NCT05425745 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: selective CETP inhibitor Area: Nutritional and Metabolic Diseases Indication: Heterozygous Familial Hypercholesterolemia (HeFH) Human Patients: 354 Sponsor: NewAmsterdam Pharma (NAMS)	Date: 12 May 2024 Quarter: Q3'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit of obicetrapib in LDL-C reduction with significantly increased toxicity-driven mortality) Commercial: FAILURE (commercially insufficient additive clinical benefit of obicetrapib in MACE or cardiovascular hospitalization with significantly increased toxicity-driven mortality)	Readout: 29 Jul 2024 Lead Time: 78 days in advance Interpretation: safe yet with 41.5% LDL-C reduction by Day 364 which is weaker than the market expected 50% LDL-C reduction.	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1510	CT1812 NCTID: NCT03507790 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: allosteric sigma-2 receptor antagonist Area: Nervous System Diseases Indication: Mild to Moderate Alzheimer's Disease Human Patients: 153 Sponsor: Cognition Therapeutics (CGTX)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit despite tolerable toxicity) Commercial: FAILURE (commercially insufficient clinical benefit inferior to donanemab/lecanemab)	Readout: 29 Jul 2024 Lead Time: 133 days in advance Interpretation: safe yet none of the key exploratory efficacy endpoints was met (consistent trend only).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1638	BLZ945 NCTID: NCT04066244 Phase: Phase 2	Date: 1 Jul 2024 Quarter: - Batch - Technical: FAILURE (statistically	Readout: 26 Jul 2024 Lead Time: 25 days in advance Interpretation: not disclosed yet trial	Correct Prediction Conclusion: statistically insignificant and commercially

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: small molecule MoA: CSF1R inhibitor Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis (ALS) Human Patients: 28 Sponsor: Novartis (NVS)	insignificant additive clinical benefit with moderate toxicity to accelerate ALS disease progression) Commercial: FAILURE (commercially insufficient additive clinical benefit in ALSFRS-R)	terminated after internal review of efficacy and toxicity available data	insufficient Classification: True Negative (TN)
1379	SAGE-324 NCTID: NCT05173012 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: steroid GABAAR PAM Area: Nervous System Diseases Indication: Essential Tremor Human Patients: 147 Sponsor: Sage Therapeutics (SAGE)	Date: 15 Dec 2023 Quarter: Q1'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 24 Jul 2024 Lead Time: 222 days in advance Interpretation: endpoints not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1404	ION582 NCTID: NCT05127226 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: intrathecal anti-UBE3A-AS ASO Area: Nervous System Diseases Indication: Angelman Syndrome Human Patients: 51 Sponsor: Ionis Pharmaceuticals (IONS)	Date: 3 Jan 2024 Quarter: Q2'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit non-superior non-inferior to GTX102)	Readout: 22 Jul 2024 Lead Time: 201 days in advance Interpretation: 97% patients have improvements in SAS-CGI-C endpoint and consistent improvements in multiple functions; advance to pivotal trial alone by Ionis.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Positive (TP)
1664	LX2006 NCTID: NCT05445323 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAVrh10-based gene therapy that deliver human FXN gene to cardiac cells Area: Nervous System Diseases Indication: Friedreich's Ataxia Human Patients: 9 Sponsor: Lexeo Therapeutics (LXEO)	Date: 7 Jul 2024 Quarter: Q3'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in cardiac fibrosis/cardiac arrhythmia/exercise tolerance despite significantly increasing FXN expression level) Commercial: FAILURE (commercially insufficient clinical benefit in cardiac fibrosis/cardiac arrhythmia/exercise tolerance)	Readout: 15 Jul 2024 Lead Time: 8 days in advance Interpretation: 11.4% LVMI reduction at month 12; which falls in the lower end of the minimal clinically meaningful improvement threshold of 10-15% reduction in LVMI over 6 to 12 months.	Correct Prediction Conclusion: statistically maybe significant yet weak clinical benefit and commercially insufficient Classification: True Negative (TN)
1175	RMC-6236 NCTID: NCT05379985 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: pan-RAS-mutation ON inhibitor Area: Neoplasms Indication: RAS Mutant Advanced Solid Tumors Human Patients: 474 Sponsor: Revolution Medicines (RVMD)	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 15 Jul 2024 Lead Time: 365 days in advance Interpretation: 20-21% ORR at week 14 vs 16% ORR achieved by Nal-IRI + 5-FU/LV for any PDAC (see add link for Nal-IRI data in Lancet) or 21% ORR achieved by Sotorasib in CodeBreak 100 trial NEJM.	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (weak ORR improvement) Classification: True Negative (TN)
1240	Eftilagimod alpha Pembrolizumab NCTID: NCT04811027 Phase: Phase 2	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit)	Readout: 12 Jul 2024 Lead Time: 312 days in advance Interpretation: 35.5% ORR vs 30.8% ORR for chemo+pembrolizumab in	Correct Prediction Conclusion: statistically significant (superior to SoC ORR) and commercially TBD (OS data)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: fusion protein biologic MoA: a Soluble LAG-3 Fusion Protein Area: Neoplasms Indication: Recurrent or Metastatic HNSCC Human Patients: 171 Sponsor: Immute (IMMP)	Commercial: SUCCESS (commercially sufficient additive clinical benefit)	CPS <1 population (Burtne et al. 2022 J. Clin Oncol).	pending) Classification: True Positive (TP)
908	AMT-130 NCTID: NCT05243017 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV gene therapy that delivers anti-HTT miRNA Area: Nervous System Diseases Indication: Early Manifest Huntington's Disease Human Patients: 15 Sponsor: uniQure (QURE)	Date: 13 May 2024 Quarter: Q3'24 Batch 8 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in UHDRS) Commercial: FAILURE (commercially insufficient clinical benefit in UHDRS)	Readout: 9 Jul 2024 Lead Time: 57 days in advance Interpretation: externally statistically significant less cUHDRS (-0.2 vs -1 at Month 24 for high-dose only (p=0.007) but not low-dose (p=0.21); no statistical improvement in motor or cognitive function even for high-dose group.	Correct Prediction Conclusion: still statistically maybe significant (not strictly placebo-controlled) and commercially insufficient (no motor cognitive function improvement) Classification: True Negative (TN)
909	AMT-130 NCTID: NCT04120493 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV gene therapy that delivers anti-HTT miRNA Area: Nervous System Diseases Indication: Early Manifest Huntington's Disease Human Patients: 36 Sponsor: uniQure (QURE)	Date: 13 May 2024 Quarter: Q3'24 Batch 8 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit in UHDRS) Commercial: FAILURE (commercially insufficient clinical benefit in UHDRS)	Readout: 9 Jul 2024 Lead Time: 57 days in advance Interpretation: externally statistically significant less cUHDRS (-0.2 vs -1 at Month 24 for high-dose only (p=0.007) but not low-dose (p=0.21); no statistical improvement in motor or cognitive function even for high-dose group.	Correct Prediction Conclusion: still statistically maybe significant (not strictly placebo-controlled) and commercially insufficient (no motor cognitive function improvement) Classification: True Negative (TN)
934	Buntanetap NCTID: NCT05357989 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: neurotoxic protein synthesis inhibitor Area: Nervous System Diseases Indication: Parkinson's Disease Human Patients: 523 Sponsor: Annovis Bio (ANVS)	Date: 24 Mar 2024 Quarter: Q2'24 Batch 13 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 2 Jul 2024 Lead Time: 100 days in advance Interpretation: primary efficacy endpoint not met in presentation rather than press release (x.com/ada.mfeuerstein/status/1808471091066581487)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1580	Descartes-08 NCTID: NCT04146051 Phase: Phase 2b Class: First-In-Class Modality: CAR-T therapy MoA: autologous anti-BCMA CAR-T therapy Area: Immune System Diseases Indication: Generalized Myasthenia Gravis Human Patients: 30 Sponsor: Cartesian Therapeutics (RNAC)	Date: 26 Apr 2024 Quarter: Q3'24 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-efgartigimod efficacy)	Readout: 2 Jul 2024 Lead Time: 67 days in advance Interpretation: 46% placebo-adjusted >=5 MGC response at week 12 (vs efgartigimod 30% placebo-adjusted >=3 MGC response at week 26 ADAPT trial).	Correct Prediction Conclusion: statistically significant and commercially sufficient superior to efgartigimod Classification: True Positive (TP)
849	RP-6306 NCTID: NCT05147350 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: oral PKMYT1 inhibitor	Date: 15 Feb 2024 Quarter: Q2'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 26 Jun 2024 Lead Time: 132 days in advance Interpretation: 12% confirmed ORR (4/33) vs 30%-50% ORR for other X+ FOLDIRI combotherpies.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 36 Sponsor: Repare Therapeutics (RPTX)	insufficient additive clinical benefit)		
1478	LYL797 NCTID: NCT05274451 Phase: Phase 1 Class: First-In-Class Modality: CAR-T therapy MoA: Epi-R-enhanced c-JUN-overexpressing anti-ROR1 CAR-T therapy Area: Neoplasms Indication: Solid Tumors Human Patients: 54 Sponsor: Lyell Immunopharma (LYEL)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS/OS) Commercial: SUCCESS (commercially sufficient clinical benefit superior to other CAR-T therapies for ROR1+ advanced solid tumors)	Readout: 26 Jun 2024 Lead Time: 129 days in advance Interpretation: 40% ORR (superior to 27% placebo-adjusted ORR by trodelvy for advanced TNBC in ASCENT study) yet with 35% grade>3 TEAEs (pneumonitis and hypoxia).	Overall Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1398	Molgramostim NCTID: NCT04544293 Phase: Phase 3 Class: First-In-Class Modality: recombinant protein biologic MoA: recombinant GM-CSF Area: Respiratory Tract Diseases Indication: Autoimmune Pulmonary Alveolar Proteinosis Human Patients: 160 Sponsor: Savara (SVRA)	Date: 1 Jan 2024 Quarter: Q2'24 Batch 5 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 26 Jun 2024 Lead Time: 177 days in advance Interpretation: lung function primary endpoint placebo-adjusted DLCO met at both 24 and 48 weeks (6 to 6.9 with p <0.001); yet 5/6 clinical benefit secondary endpoints (SRGQ total/activity scores and exercise capacity) not met at 24 weeks and 48 weeks with abnormal duration-response relationship.	Overall Correct Prediction Conclusion: statistically significant yet commercially insufficient clinical benefit Classification: True Negative (TN)
1246	WVE-003 NCTID: NCT05032196 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: stereopure antisense oligonucleotide MoA: SNP3 mtHTT mRNA oligonucleotide Area: Nervous System Diseases Indication: Huntington's Disease Human Patients: 47 Sponsor: Wave Life Sciences (WVE)	Date: 21 Nov 2023 Quarter: 2H'23 Batch 28 Technical: partial SUCCESS (statistically significant clinical benefit in reducing mHTT protein level); partial FAILURE (statistically insignificant clinical benefit in modifying disease progression) Commercial: FAILURE (commercially insufficient clinical benefit in modifying disease progression despite significant reduction in mHTT protein)	Readout: 25 Jun 2024 Lead Time: 217 days in advance Interpretation: -46% mean reduction in mHTT yet insignificant improvement for TMS.	Correct Prediction Conclusion: statistically significant in mHTT and commercially insufficient in TMS Classification: True Negative (TN)
1585	Xevinapant (Debio 1143) Cisplatin Intensity Modulation Radiation Therapy (IMRT) Placebo NCTID: NCT04459715 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral IAP inhibitor Area: Neoplasms Indication: Squamous Cell Carcinoma of the Head and Neck Human Patients: 730 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: Q3'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 Lead Time: 47 days in advance Interpretation: unlikely to meet EFS primary endpoints and discontinued.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1610	Xevinapant IMRT Placebo NCTID: NCT05386550 Phase: Phase 3 Class: First-In-Class Modality: small molecule	Date: 14 May 2024 Quarter: - Batch - Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in DFS)	Readout: 24 Jun 2024 Lead Time: 41 days in advance Interpretation: unlikely to meet DFS primary endpoints and discontinued.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: oral IAP inhibitor Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 166 Sponsor: Merck KGaA (MKKGY)	Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)		Classification: True Negative (TN)
407	Trilaciclib Placebo Gemcitabine Carboplatin NCTID: NCT04799249 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: TNBC - Triple-Negative Breast Cancer Human Patients: 194 Sponsor: G1 Therapeutics (GTHX)	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit in OS) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 Lead Time: 140 days in advance Interpretation: OS endpoint not met	Missed Prediction Note: due to suboptimal combotherapy causal modeling in metastatic TNBC that has been permanently corrected... Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
901	ALT-801 NCTID: NCT05295875 Phase: Phase 2 Class: Best-In-Class Modality: peptide biologic MoA: dual GLP1/glucagon receptor agonist Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 391 Sponsor: Altimmune (ALT)	Date: 20 Nov 2023 Quarter: 2H'23 Batch 30 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 23 Jun 2024 Lead Time: 216 days in advance Interpretation: -13.2% placebo-adjusted weight loss at week 48 (vs -20% placebo-adjusted weight loss at week 48 for tirzepatide 15mg).	Correct Prediction Conclusion: statistically significant and commercially insufficient inferior to tirzepatide Classification: True Negative (TN)
1498	ZP8396 NCTID: NCT05613387 Phase: Phase 1 Class: First-In-Class Modality: peptide biologic MoA: long-lasting amylin analog Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 68 Sponsor: Zealand Pharma (ZEAL.CO)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in weight loss) Commercial: FAILURE (commercially insufficient clinical benefit for repeated-dose ZP8396; which is inferior to semaglutide with increasing toxicity for elderly obese population with comorbidities)	Readout: 20 Jun 2024 Lead Time: 106 days in advance Interpretation: 6.9% weight loss in 16 weeks among male adults with 49 years old vs 13.1% weight loss in 12 weeks by Amycretin.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
776	JZP385 NCTID: NCT05122650 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: t-type calcium channel antagonist Area: Nervous System Diseases Indication: Essential Tremor Human Patients: 420 Sponsor: Jazz Pharmaceuticals (JAZZ)	Date: 21 Nov 2023 Quarter: Q1'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Jun 2024 Lead Time: 212 days in advance Interpretation: endpoints not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
557	PTC518 NCTID: NCT05358717 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: HTT mRNA degradation Area: Nervous System Diseases Indication: Huntington's Disease	Date: 5 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in lowering tHTT level) Commercial: FAILURE (commercially insufficient clinical benefit in	Readout: 20 Jun 2024 Lead Time: 107 days in advance Interpretation: 43% mHTT lowering for 10mg; TMS (2.0 points worsening for 5mg and 1.3 points worsening for 10mg vs. 4.9 points worsening for placebo).	Correct Prediction Conclusion: statistically significant and commercially insufficient (TMS and UHDRS scores are both functional endpoints; pending for UHDRSdata) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 252 Sponsor: PTC Therapeutics (PTCT)	UHDRS-TFC score)		
1079	ZN-c3 NCTID: NCT04814108 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: Uterine Serous Carcinoma Human Patients: 76 Sponsor: Zentaris Pharmaceuticals (ZNTL)	Date: 25 May 2023 Quarter: Q2'23 Batch 21a Technical: FAILURE (statistically insignificant clinical efficacy in ORR in placebo-controlled trial and moderate clinical toxicity) Commercial: FAILURE (commercially insufficient clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1077	ZN-c3 NCTID: NCT04158336 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: Solid Tumors Human Patients: 146 Sponsor: Zentaris Pharmaceuticals (ZNTL)	Date: 25 May 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical efficacy and high clinical toxicity) Commercial: FAILURE (commercially insufficient clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1078	ZN-c3 NCTID: NCT05128825 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: High-Grade Serous Ovarian; Fallopian Tube or Primary Peritoneal Cancer Human Patients: 102 Sponsor: Zentaris Pharmaceuticals (ZNTL)	Date: 25 May 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1464	TSHA-102 NCTID: NCT06152237 Phase: Phase 1 Class: First-In-Class Modality: AAV9-based gene therapy MoA: scAAV9-delivered miniMECP2 gene therapy Area: Nervous System Diseases Indication: Rett Syndrome Human Patients: 6 Sponsor: Taysha Gene Therapies (TSHA)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 18 Jun 2024 Lead Time: 125 days in advance Interpretation: weak efficacy in seizure reduction (none is seizure free without anti-seizure medication).	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: True Negative (TN)
353	Lumateperone NCTID: NCT05061706 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: D1R/D2R/D4R/5TH2AR antagonist Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 480	Date: 9 Jan 2024 Quarter: Q2'24 Batch 5 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 18 Jun 2024 Lead Time: 161 days in advance Interpretation: 4.5 point placebo-adjusted reduction in MADRS.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Intra-Cellular Therapies (ITCI)			
1440	AV-101 NCTID: NCT05036135 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: dry powder inhaled formulation MoA: inhaled imatinib as a tyrosine kinase inhibitor Area: Respiratory Tract Diseases Indication: Pulmonary Arterial Hypertension Human Patients: 462 Sponsor: Aerovate Therapeutics (AVTE)	Date: 27 Jan 2024 Quarter: Q2'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PVR); partial FAILURE (statistically insignificant clinical benefit in 6MWD) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 17 Jun 2024 Lead Time: 142 days in advance Interpretation: no dose met the primary efficacy endpoint PVR and no dose achieved minimally clinical meaningful improvement in 6MWD (30 meters).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1593	Soticlestat NCTID: NCT04940624 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CH24H inhibitor Area: Nervous System Diseases Indication: Dravet Syndrome Human Patients: 144 Sponsor: Takeda Pharmaceutical / Ovid Therapeutics (TAK / OVID)	Date: 11 May 2024 Quarter: Q3'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit to SoC) Commercial: FAILURE (commercially insufficient additive clinical benefit with inferior-to-cannabidiol-or-fenfluramine efficacy in seizure frequency reduction)	Readout: 17 Jun 2024 Lead Time: 37 days in advance Interpretation: primary endpoint not met despite meeting several secondary endpoints.	Correct Prediction Conclusion: statistically insignificant and inferior to SoC Classification: True Negative (TN)
965	Efgartigimod NCTID: NCT05633407 Phase: Phase 2 Class: First-In-Class Modality: antibody fragment biologic MoA: anti-FcRn antibody fragment Area: Nervous System Diseases Indication: Postural Orthostatic Tachycardia Syndrome Human Patients: 53 Sponsor: argenx (ARGX)	Date: 4 Jul 2023 Quarter: 2H'23 Batch 9 Technical: partial SUCCESS (statistically significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 17 Jun 2024 Lead Time: 349 days in advance Interpretation: no clinically meaningful improvements compared to placebo on both total MaPS score and COMPASS31 and trial discontinued.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1359	CABA-201 NCTID: NCT06121297 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: anti-CD19 CAR T Area: Immune System Diseases Indication: Systemic Lupus Erythematosus (SLE) Human Patients: 12 Sponsor: Cabaletta Bio (CABA)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient clinical benefit despite moderate toxicity)	Readout: 14 Jun 2024 Lead Time: 197 days in advance Interpretation: CABA201 reduced SLEDAI-2K score from 26 at baseline to 10 at week 4 of follow-up; an LN patient experienced dose-limiting Grade 4 ICANS.	Overall Correct Prediction Conclusion: statistically significant and commercially sufficient (despite moderate toxicity) Classification: True Positive (TP)
614	SL-172154 NCTID: NCT05275439 Phase: Phase 1 Class: First-In-Class Modality: fusion protein biologic MoA: CD47-CD40 fusion protein Area: Neoplasms Indication: Acute Myeloid Leukemia (AML) / Myelodysplastic Syndrome (MDS) Human Patients: 160	Date: 25 Jun 2023 Quarter: 2H'23 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 Jun 2024 Lead Time: 355 days in advance Interpretation: 67% ORR (MDS vs 73% ORR and 73% CR/mCR for azacitidine) and 43% ORR (AML; vs 69% ORR and 45% CR for a azacitidine + magrolimab as 1L for TP53 mutant AML).	Correct Prediction Conclusion: no additive efficacy compared with SoC 1L; thus commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Shattuck Labs (STTK)			
940	SNDX-5613 (Revumenib) Chemotherapy Regimen 1 Chemotherapy Regimen 2 NCTID: NCT05326516 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: menin/KMT2A inhibitor Area: Neoplasms Indication: R / R A c u t e Human Patients: 30 Sponsor: Syndax Pharmaceuticals (SNDX)	Date: 18 Jun 2023 Quarter: 2H'23 Batch 13 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 Jun 2024 Lead Time: 362 days in advance Interpretation: 52% confirmed CR (vs 81% CR for CLT019).	Correct Prediction Conclusion: statistically significant yet non-superior compared with SoC CAR-T; thus commercial insufficient Classification: True Negative (TN)
1001	AOC 1020 NCTID: NCT05747924 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: anti-DUX4 siRNA oligonucleotide Area: Musculoskeletal Diseases Indication: Facioscapulohumeral Muscular Dystrophy (FSHD) Human Patients: 72 Sponsor: Avidity Biosciences (RNA)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Jun 2024 Lead Time: 195 days in advance Interpretation: 50% mean reduction in DUX4-targeted genes; yet with statistically insignificant trends of functional improvement.	Correct Prediction Conclusion: statistically significant and commercially insufficient (weak functional efficacy) Classification: True Negative (TN)
1414	PF-06939926 NCTID: NCT04281485 Phase: Phase 3 Class: Best-In-Class Modality: gene therapy MoA: rAAV9 vector carrying a minidystrophin gene Area: Musculoskeletal Diseases Indication: Duchenne Muscular Dystrophy (DMD) Human Patients: 122 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-SRP9001 efficacy)	Readout: 12 Jun 2024 Lead Time: 149 days in advance Interpretation: statistically insignificant for all primary/secondary endpoints.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient (SRP9001 at least meet some secondary endpoints) Classification: True Negative (TN)
1489	AFM13 AB-101 Cyclophosphamide Fludarabine Interleukin-2 NCTID: NCT05883449 Phase: Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: CD30 x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Relapsed or Refractory Hodgkin Lymphoma Peripheral T Cell Lymphoma Human Patients: 154 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Jun 2024 Lead Time: 104 days in advance Interpretation: 87.5% ORR (lower than 100% ORR for AFMD alone).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1260	Povetacicept (ALPN-303) NCTID: NCT05732402 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: Fc fusion protein MoA: dual APRIL/BAFF antagonist	Date: 2 Oct 2023 Quarter: 2H'23 Batch 19 Technical: SUCCESS (statistically significant clinical benefit for proteinuria) Commercial: FAILURE (commercially	Readout: 12 Jun 2024 Lead Time: 254 days in advance Interpretation: -47% UPCR and -0.2mL eGFR at 24 weeks (vs -18% UPCR and +1.0mL eGFR at 24 weeks by Tarpeyo).	Correct Prediction Conclusion: statistically significant in UPCR and commercially insufficient for eGFR Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Immune System Diseases Indication: immunoglobulin A (IgA) nephropathy; membranous nephropathy; lupus-related kidney disease (lupus nephritis); anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis Human Patients: 56 Sponsor: ALPN Alpine Immune Sciences / Vertex Pharmaceuticals (ALPN (VRTX))	insufficient clinical benefit due to low clinical efficacy on eGFR)		
1381	SAGE-718 NCTID: NCT05358821 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: NMDAR PAM Area: Nervous System Diseases Indication: Huntington's Disease Human Patients: 69 Sponsor: Sage Therapeutics (SAGE)	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 11 Jun 2024 Lead Time: 52 days in advance Interpretation: only trends of functional improvement IN HD-CAB thus statistically insignificant.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
647	Renal Autologous Cell Therapy NCTID: NCT05018416 Phase: Phase 2 Class: First-In-Class Modality: Cell Therapy MoA: renal autologous kidney progenitor cell therapy Area: Nutritional and Metabolic Diseases and Urogenital Diseases Indication: Type 1 or 2 Diabetes and Chronic Kidney Disease Human Patients: 53 Sponsor: ProKidney (PROK)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 10 Jun 2024 Lead Time: 117 days in advance Interpretation: average eGFR change from baseline to 18 months was -1.3 ml/min/1.73m2 (given no-zero placebo average eGFR change; the placebo-adjusted eGFR change of REACT would probably be smaller than the SoC Empagliflozin (DOI-10.1056/NEJMoa2204233).	Overall Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
543	Relacorilant NCTID: NCT03697109 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral non-steroidal glucocorticoid receptor antagonist Area: Endocrine System Diseases Indication: Cushing Syndrome Human Patients: 152 Sponsor: Corcept Therapeutics (CORT)	Date: 22 Oct 2022 Quarter: Q3'24 Batch 1 Technical: FAILURE (statistical insignificant clinical benefit in the randomized-withdrawal phase) Commercial: FAILURE (commercially insufficient clinical benefit in the randomized-withdrawal phase)	Readout: 7 Jun 2024 Lead Time: 594 days in advance Interpretation: primary endpoint loss of response met with borderline statistical significance (p=0.02) secondary endpoint 24h SBP achieved statistical significance (P=0.0025) yet 24h DBP didn't achieve statistical significance (P=0.046); neither body weight (P=0.09) nor HbA1c (P=0.04) achieved statistical significance.	Overall Correct Prediction Conclusion: statistically borderline significant and commercially insufficient Classification: True Negative (TN)
1492	BMF-219 NCTID: NCT06152042 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral small molecule MENIN inhibitor Area: Nutritional and Metabolic Diseases Indication: Type 1 Diabetes Mellitus Human Patients: 190 Sponsor: Biomea Fusion (BMEA)	Date: 29 Feb 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit for T1DM patients)	Readout: 6 Jun 2024 Lead Time: 98 days in advance Interpretation: full clinical hold due to hepatotoxicity	Correct Prediction Conclusion: statistically insignificant and commercially insufficient (hepatotoxicity) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1005	4D-710 NCTID: NCT05248230 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: aerosol delivered human-mAb-resistant AAV transgene payload expressing CFTR Area: Respiratory Tract Diseases Indication: Cystic Fibrosis Human Patients: 24 Sponsor: 4D Molecular Therapeutics (FDMT)	Date: 11 May 2024 Quarter: Q3'24 Batch 5 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 6 Jun 2024 Lead Time: 26 days in advance Interpretation: achieved 5-6% ppFEV1 from baseline by month 12; which is inferior to vertex's SoC's 14% improvement in 4 weeks.	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
1447	Inebilizumab NCTID: NCT04540497 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD19 mAb inhibitor Area: Immune System Diseases Indication: IgG4 Related Disease Human Patients: 135 Sponsor: Amgen (AMGN)	Date: 5 Feb 2024 Quarter: Q3'24 Batch 11 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 5 Jun 2024 Lead Time: 121 days in advance Interpretation: -87% risk reduction in IgG4-RD flare compared with placebo.	Missed Prediction Note: due to suboptimal IgG4-RD disease model that has been permanently corrected. Conclusion: statistically significant and commercially sufficient Classification: False Negative (FN)
1481	S-309309 NCTID: NCT05925114 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MGAT2 inhibitor Area: Nutritional and Metabolic Diseases Indication: Obesity Human Patients: 365 Sponsor: Shionogi & Co (SGIOY)	Date: 26 Feb 2024 Quarter: Q2'24 Batch 8 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in weight loss) Commercial: FAILURE (commercially insufficient clinical benefit inferior to semaglutide/tirzepatide)	Readout: 4 Jun 2024 Lead Time: 99 days in advance Interpretation: S309309 achieved less than 5% absolute weight reduction in week 24; inferior to semaglutide 10.9% absolute weight reduction in week 24 (see 10.1001/jamanetworkopen.2022.31982)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient (inferior to semaglutide in weight loss efficacy) Classification: True Negative (TN)
846	EQ101 NCTID: NCT05589610 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: tri-specific IL2/IL9/IL15 inhibitor Area: Skin and Connective Tissue Diseases Indication: Moderate to Severe Alopecia Areata Human Patients: 36 Sponsor: Equillium (EQ)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 4 Jun 2024 Lead Time: 107 days in advance Interpretation: 20-29% <20 SALT score at week 24 achieved by EQ101 (vs 23% <20 SALT score at week 24 achieved by ritectinib 50mg King et al. 2023 Lancet in NCT03732807).	Correct Prediction Conclusion: statistically significant and commercially sufficient (only one approved treatment so far) Classification: True Positive (TP)
475	VK2809 NCTID: NCT04173065 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: liver-selective thyroid hormone receptor beta agonist Area: Nutritional and Metabolic Diseases Indication: NASH - Nonalcoholic Steatohepatitis Human Patients: 248 Sponsor: Viking Therapeutics (VKTX)	Date: 16 Oct 2023 Quarter: Q1'24 Batch 4 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 4 Jun 2024 Lead Time: 232 days in advance Interpretation: 39.7% NASH resolution without worsening of fibrosis combined and 17% fibrosis improvement without worsening of NASH (vs 16-20% and 10-12% for resmetirom).	Correct Prediction Conclusion: statistically significant and commercially sufficient (superior to resmetirom) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
344	ANX005 NCTID: NCT04701164 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: C1q mAb inhibitor Area: Immune System Disease Indication: Guillain-Barre Syndrome Human Patients: 216 Sponsor: Annexon (ANNX)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 12 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 4 Jun 2024 Lead Time: 165 days in advance Interpretation: primary endpoint (GBS-DS) with lower dosage 30mg/kg yet not met with higher dosage 75mg/kg; none of the secondary endpoints met.	Correct Prediction Conclusion: statistically mostly insignificant (negative dose-response relationship) and commercially insufficient Classification: True Negative (TN)
661	TransCon IL-2^{2/3} Pembrolizumab Chemotherapy drug TransCon TLR7/8 Agonist Surgery NCTID: NCT05081609 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: protein prodrug MoA: IL-2 ^{2/3} agonist Area: Neoplasms Indication: Solid Tumor Malignancies Human Patients: 473 Sponsor: Ascendis Pharma (ASND)	Date: 12 Apr 2023 Quarter: Q2'23 Batch 8 Technical: SUCCESS (mono); SUCCESS (combo + pembrolizumab); SUCCESS (combo + chemo); FAILURE (combo + TransCon TLR7/8) Commercial: SUCCESS (mono); SUCCESS (combo + pembrolizumab); SUCCESS (combo + chemo); FAILURE (combo + TransCon TLR7/8)	Readout: 3 Jun 2024 Lead Time: 418 days in advance Interpretation: 40% ORR (IL2 + TLR7/8) for advanced melanoma (40-48% for BRAF-mutated BRAF/MEK inhibitors or 29% for BRAF-wild-type ipilimumab + pembrolizumab); 25% ORR (IL2) for colorectal cancer (vs 12-16.4% ORR for regorafenib + ICI or cetuximab + chemo); 100% ORR (IL2 + pembro) for SCLC (40% ORR for tarlatamab).	Correct Prediction Conclusion: statistically significant and commercially partially insufficient (IL2 + TLR7/8) yet commercially partially sufficient (other arms) Classification: True Negative (TN)
1060	CRN04894 NCTID: NCT05804669 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: oral ACTH MC2R antagonist Area: Endocrine System Diseases Indication: ACTH-Dependent Cushing's Syndrome (ADCS) Human Patients: 18 Sponsor: Crinetics Pharmaceuticals (CRNX)	Date: 14 Aug 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 294 days in advance Interpretation: 100% Urinary free cortisol level for ADCS.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1208	CRN04894 NCTID: NCT05907291 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral ACTH MC2R antagonist Area: Urogenital Diseases Indication: Congenital Adrenal Hyperplasia (CAH) Human Patients: 30 Sponsor: Crinetics Pharmaceuticals (CRNX)	Date: 14 Aug 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 294 days in advance Interpretation: 100% A4 normal for CAH.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
793	ARO-APOC3 NCTID: NCT05089084 Phase: Phase 3 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: siRNA-GalNAc conjugate that suppresses APOC3 mRNA Area: Nutritional and Metabolic Diseases Indication: Familial Chylomicronemia Human Patients: 30	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 110 days in advance Interpretation: 80% triglyceride reduction; 94% APOC3 reduction.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 75 Sponsor: Arrowhead Pharmaceuticals (ARWR)			
1266	GSBR-1290 NCTID: NCT05762471 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small-molecule MoA: an oral and biased small molecule GLP1R agonist Area: Nutritional and Metabolic Diseases Indication: Overweight or Obesity Type2 Diabetes Mellitus Human Patients: 142 Sponsor: Structure Therapeutics (GPCR)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in weight loss) Commercial: partial SUCCESS (commercially insufficient clinical benefit inferior to VK2735 for obesity)	Readout: 3 Jun 2024 Lead Time: 89 days in advance Interpretation: 6.2-6.9% placebo-adjust weight loss at week 12 (vs 13.1% at week 12 by Amycretin (on a par with VK2735) and 6-7% by orforglipron at week 12).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1546	CNTY-101 IL-2 Lymphodepleting Chemotherapy NCTID: NCT05336409 Phase: Phase 1 Class: First-In-Class Modality: CAR-NK cell therapy MoA: allogeneic anti-CD19 CAR-iNK cells with Allo-Evasion edits; IL-15 support; and EGFR safety switch Area: Neoplasms Indication: CD19-Positive B-Cell Malignancies Human Patients: 75 Sponsor: Century Therapeutics (IPSC)	Date: 14 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to anti-CD19 CAR-T cell therapies)	Readout: 3 Jun 2024 Lead Time: 50 days in advance Interpretation: 40-60% ORR (vs 74.1% ORR Anti-CD19 CAR-T cell therapy HR001).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
910	Tildacerfont NCTID: NCT05370521 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CRF1R antagonist Area: Neoplasms Indication: Polycystic Ovary Syndrome Human Patients: 27 Sponsor: Spruce Biosciences (SPRB)	Date: 7 Aug 2023 Quarter: 2H'23 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 301 days in advance Interpretation: significant reduction in DHEAS -12.4% vs placebo +5.7% was observed (p = 0.020; vs -12% by metformin).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior) Classification: True Negative (TN)
1334	Darovasertib NCTID: NCT05907954 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: potent selective oral PKC inhibitor Area: Neoplasms Indication: Localized Ocular Melanoma Human Patients: 82 Sponsor: IDEAYA Biosciences (IDYA)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 77 days in advance Interpretation: 75% confirmed eye saved.	Correct Prediction Conclusion: statistically significant and commercially sufficient (no neoadjuvant SoC established for ocular melanoma) Classification: True Positive (TP)
1494	Biological NTLA-2002 Normal Saline IV Administration NCTID: NCT05120830 Phase: Phase 1 Phase 2 Class: First-In-Class	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit)	Readout: 2 Jun 2024 Lead Time: 91 days in advance Interpretation: -98% mean monthly HAE attacks vs -85% by PHVS's deucricitbant.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: gene therapy MoA: LNP-delivered CRISPR/CAS9-based anti-KLKB1 gene therapy Area: Cardiovascular Diseases Indication: Hereditary Angioedema Human Patients: 37 Sponsor: Intellia Therapeutics (NTLA)	Commercial: SUCCESS (commercially sufficient clinical benefit)		
506	AB680 Etrumadenant Zimberelimab Bevacizumab m-FOLFOX-6 regimen Regorafenib NCTID: NCT04660812 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective dual antagonist of the A2a and A2b receptors Area: Neoplasms Indication: Metastatic Colorectal Cancer Human Patients: 227 Sponsor: Gilead Sciences / Arcus Bioscience (GILD/RCUS)	Date: 18 Jun 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 2 Jun 2024 Lead Time: 350 days in advance Interpretation: 17.3% ORR and 19.7 months mOS (vs 19% ORR and 21.4months OS by the FOLFIRI/bevacizumab alone without zimberelimab as 2L mCRC treatment in the SPIRITT trial).	Overall Correct Prediction Conclusion: statistically significant yet commercially insufficient (non-superior) pending more cohorts data Classification: True Negative (TN)
1094	Evorpcept (ALX148) Enfortumab Vedotin NCTID: NCT05524545 Phase: Phase 1 Class: First-In-Class Modality: fusion protein biologic MoA: anti-CD47 blocker Area: Neoplasms Indication: Urothelial Carcinoma Human Patients: 30 Sponsor: ALX Oncology (ALXO)	Date: 22 Jul 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 2 Jun 2024 Lead Time: 316 days in advance Interpretation: 50% ORR (20 patients receiving treatments) vs. 64.5% ORR for pembrolizumab + enfortumab).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1495	Sacituzumab Govitecan-hziy Paclitaxel Docetaxel Vinflunine NCTID: NCT04527991 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload for lysosomal-degradation-mediated intracellular release Area: Neoplasms Indication: Metastatic or Locally Advanced Unresectable Urothelial Cancer Human Patients: 696 Sponsor: Gilead Sciences (GILD)	Date: 5 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-chemotherapy efficacy in OS)	Readout: 30 May 2024 Lead Time: 86 days in advance Interpretation: OS primary endpoint not met.	Missed Prediction Note: due to suboptimal drug MoA modeling that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient (non-superior) Classification: False Positive (FP)
792	ARO-APOC3 NCTID: NCT04998201 Phase: Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: siRNA-GalNAc conjugate that suppresses APOC3 mRNA Area: Nutritional and Metabolic Diseases Indication: Mixed Dyslipidemia Human Patients: 353	Date: 14 Feb 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 104 days in advance Interpretation: 50-62% triglyceride reduction; superior to 30-50% achieved by SoC (Fibrates).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Arrowhead Pharmaceuticals (ARWR)			
1461	ARCT-032 NCTID: NCT05712538 Phase: Phase 1 Class: First-In-Class Modality: mRNA medicine MoA: LNP-delivered CTFR mRNA medicine Area: Respiratory Tract Diseases Indication: Cystic Fibrosis Human Patients: 38 Sponsor: Arcturus Therapeutics (ARCT)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 104 days in advance Interpretation: 4% FEV1 improvement at day 8 (no SoC for mutation-agnostic CF).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
432	Brensocatib NCTID: NCT04594369 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral reversible DDP-1 inhibitor Area: Respiratory Tract Diseases Indication: Non-Cystic Fibrosis Bronchiectasis Human Patients: 1767 Sponsor: Insmed (INSM)	Date: 1 Jan 2024 Quarter: Q2'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with reduced efficacy from increased dosage) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 148 days in advance Interpretation: 19.4%-21.1% reduction in APE (vs 30%-50% reduction achieved by azithromycin in similar clinical settings); clearly weak efficacy (vs azithromycin) and clearly negative dose-response relationship (in both primary and other secondary endpoints).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
406	Trilaciclib in Patients Receiving Sacituzumab Govitecan-hziy NCTID: NCT05113966 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: Triple Negative Breast Cancer Human Patients: 30 Sponsor: G1 Therapeutics (GTHX)	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit for Trolvelvy)	Readout: 28 May 2024 Lead Time: 396 days in advance Interpretation: 17.9 mOS vs 12.1 OS (trolvelvy alone).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
435	Treprostinil Palmitil NCTID: NCT05176951 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: synthetic prostacyclin analog Area: Respiratory Tract Diseases Indication: Pulmonary Hypertension Human Patients: 39 Sponsor: Insmed (INSM)	Date: 1 Jan 2024 Quarter: Q1'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 148 days in advance Interpretation: significant better tolerability than placebo and 30 meter placebo-adjusted 6MWD improvement (exploratory endpoint with large CI).	Correct Prediction Conclusion: statistically significant and commercially sufficient for phase 2a Classification: True Positive (TP)
1303	IK-930 NCTID: NCT05228015 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: oral TEAD inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 198 Sponsor: Ikena Oncology (IKNA)	Date: 31 Oct 2023 Quarter: 2H'23 Batch 25 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 210 days in advance Interpretation: 0% ORR.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
1542	CG0070 Pembrolizumab Injection n-dodecyl-B-D-maltoside NCTID: NCT04387461 Phase: Phase 2 Class: First-In-Class Modality: oncolytic virus therapy MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene Area: Neoplasms Indication: Non-Muscle Invasive Bladder Cancer Human Patients: 35 Sponsor: CG Oncology (CGON)	Date: 15 Apr 2023 Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit with superior-to-pembrolizumab-monotherapy efficacy in CR/PFS/OS)	Readout: 24 May 2024 Lead Time: 405 days in advance Interpretation: 54% CR (vs 42% CR for pembrolizumab alone).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1587	M9140 M9140 Bevacizumab Capecitabine NCTID: NCT05464030 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-CEACAM5 ADC that delivers a payload inhibiting TOP1 Area: Neoplasms Indication: Colorectal Cancer Human Patients: 200 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet weak (additive) clinical benefit in ORR) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS)	Readout: 23 May 2024 Lead Time: 15 days in advance Interpretation: 7.5% cORR and 12.9-13.9 months OS and 15% TEAE discontinuation (vs 39% ORR for SoC FOLFOX + bevacizumab) (Source-ASCO abstract 231480).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
993	sigvotatug vedotin (SGN-B6A) pembrolizumab cisplatin carboplatin NCTID: NCT04389632 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-alphavbeta6 integrin ADC that delivers MMAE as payload Area: Neoplasms Indication: Carcinoma Non-Small Cell Lung Squamous Cell Carcinoma of Head and Neck HER2 Negative Breast Neoplasms Esophageal Squamous Cell Carcinoma Esophageal Adenocarcinoma Gastroesophageal Junction Adenocarcinoma Ovarian Neoplasms Cutaneous Squamous Cell Cancer Exocrine Pancreatic Adenocarcinoma Urinary Bladder Neoplasms Uterine Cervical Neoplasms Stomach Neoplasms Human Patients: 824 Sponsor: Pfizer (PFE)	Date: 15 Apr 2023 Quarter: Q2'23 Batch 14 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (superior to anti-TROP2 ADC)	Readout: 23 May 2024 Lead Time: 404 days in advance Interpretation: 20% ORR NSCLC and 3.5 months PFS and 13% TEAE discontinuation (vs 17% ORR for Trodelvy Heist et al. Camidge 2017 J Clinical Onco).	Correct Prediction Conclusion: statistically significant and commercially numerically superior to anti-TROP2 ADC Classification: True Positive (TP)
1422	Brentuximab Vedotin With Pembrolizumab NCTID: NCT04609566 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-CD30 ADC with MMAE as payload Area: Neoplasms	Date: 15 Jan 2024 Quarter: Q1'24 Batch 5 Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit to pembrolizumab more for melanoma than for NSCLC or HNSCC) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 129 days in advance Interpretation: 13-21% ORR and 12.9-13.9 months OS and 17% TEAE discontinuation (vs 11.5-12 months OS for chemo alone or more for chemo+X).	Correct Prediction Conclusion: statistically significant and commercially non-superior to SoC (chemo alone) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Melanoma Non-small Cell Lung Cancer Squamous Cell Carcinoma of the Head and Neck Human Patients: 140 Sponsor: Pfizer (PFE)	with non-superior-to-SoC efficacy in ORR/PFS/OS)		
1420	PF-07248144 Fulvestrant Letrozole Palbociclib PF-07220060 NCTID: NCT04606446 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: anti-KAT6A/KAT6B inhibitor Area: Neoplasms Indication: Locally Advanced or Metastatic ER+ HER2- Breast Cancer Locally Advanced or Metastatic Castration-resistant Prostate Cancer Locally Advanced or Metastatic Non-small Cell Lung Cancer Human Patients: 186 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 129 days in advance Interpretation: 11.4% ORR (mono 5 prior therapy) and 30.4% ORR (PF07248144 + fulvestrant 1 prior therapy) vs 7-10% fulvestrant (mono) vs 52.3% ORR enhertu destiny-breast04.	Overall Correct Prediction Conclusion: statistically significant and commercially non-superior to SoC (enhertu) Classification: True Negative (TN)
1292	AN0025 and Chemoradiotherapy NCTID: NCT05191667 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: PGE2 EP4 inhibitor Area: Neoplasms Indication: Esophageal Cancer Human Patients: 32 Sponsor: Adlai Nortye (ANL)	Date: 19 Oct 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 217 days in advance Interpretation: 50% ORR (6/12) vs 63.5% ORR (1L tislelizumab + chemo; 68-88% ORR for CRT alone doi- 10.3390/cancers15010010).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
428	AFM24 Atezolizumab 840 MG in 14 ML Injection NCTID: NCT05109442 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: EGFR x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Selected Advanced/Metastatic EGFR-expressing Cancers Human Patients: 148 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 23 May 2024 Lead Time: 84 days in advance Interpretation: 6.6% ORR and 5.9 month PFS vs 35-50% ORR and 4.7-6.4 month PFS for SoC (nintedanib plus docetaxel VARGADO study doi- 10.1016/j.esmoop.2023.100879).	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to SoC) Classification: True Negative (TN)
1025	BLU-222 Carboplatin Ribociclib Fulvestrant NCTID: NCT05252416 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: CDK2 inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 366 Sponsor: Blueprint Medicines (BPMC)	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy or combination therapy)	Readout: 23 May 2024 Lead Time: 391 days in advance Interpretation: <5% ORR (unconfirmed) vs 22-23% ORR for SoC (16% ORR for chemo & 37-55% ORR enhertu).	Correct Prediction Conclusion: statistically significant and commercially inferior to SoC Classification: True Negative (TN)
1196	CTX-471 pembrolizumab NCTID: NCT03881488	Date: 26 Jul 2023 Quarter: 2H'23 Batch 8	Readout: 23 May 2024 Lead Time: 302 days in advance	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: CD137 agonist Area: Neoplasms Indication: Metastatic or Locally Advanced Malignancies Human Patients: 157 Sponsor: Compass Therapeutics (CMPX)	Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit yet maybe non-superior to SoC)	Interpretation: 26% ORR vs 22-23% ORR for SoC (ARX517); OS data pending.	and commercially TBD Classification: True Positive (TP)
764	ARV-766 Part A&B ARV-766 + Abiraterone Part C&D NCTID: NCT05067140 Phase: Phase 1 Class: First-In-Class Modality: PROTAC MoA: PROTAC-based AR remover Area: Neoplasms Indication: Metastatic Prostate Cancer Human Patients: 220 Sponsor: Arvinas (ARVN)	Date: 13 May 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in PSA/PFS) Commercial: SUCCESS (commercially sufficient clinical benefit for the ARV766 + abiraterone combotherapy in OS)	Readout: 23 May 2024 Lead Time: 10 days in advance Interpretation: 50% PSA50 and 10% TEAE-related discontinuation vs 45% PSA50 for docetaxel doi-10.1002/pros.22844.	Correct Prediction Conclusion: statistically significant and commercially sufficient TBD Classification: True Positive (TP)
1122	KT-253 NCTID: NCT05775406 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: MDM degrader Area: Neoplasms Indication: relapsed or refractory (R/R) high grade myeloid malignancies; acute lymphocytic leukemia (ALL); R/R lymphoma; and R/R solid tumors Human Patients: 70 Sponsor: Kymera Therapeutics (KYMR)	Date: 14 Aug 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to SoC)	Readout: 23 May 2024 Lead Time: 283 days in advance Interpretation: 15.8% ORR far lower than 40% ORR by SoC (doi-10.1177/2040620720955006).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1462	MCLA-158 + Pembrolizumab NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L HNSCC Human Patients: 567 Sponsor: Merus (MRUS)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Readout: 23 May 2024 Lead Time: 99 days in advance Interpretation: 67% ORR for combo superior to 27.3% ORR for SoC.	Correct Prediction Conclusion: statistically significant and commercially TBD (pending OS data) Classification: True Positive (TP)
419	Aglatimagene besadenovec (CAN-2409) NCTID: NCT04495153 Phase: Phase 2 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: Stage III/IV NSCLC Human Patients: 90 Sponsor: Candel Therapeutics (CADL)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS/OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 44 days in advance Interpretation: 20.6 months mOS (vs 11.6 mOS by docetaxel in a similar setting; yet the data's rigor has been questioned; and the SoC may be docetaxel + X combo (doi.org/10.1136/esmoopen-2017-000236).	Correct Prediction Conclusion: statistically significant and commercially maybe insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
977	MCLA-145 NCTID: NCT03922204 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-L1 and anti-CD137 bispecific antibody Area: Neoplasms Indication: Advanced or Metastatic Malignancies Human Patients: 118 Sponsor: Merus (MRUS)	Date: 16 Jun 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit anti-PD1 mono clinical efficacy)	Readout: 23 May 2024 Lead Time: 342 days in advance Interpretation: 9.6% ORR for mono and 10.5% ORR for combo.	Correct Prediction Conclusion: statistically significant and partially commercially sufficient (ORR is superior to pembrolizumab monotherapy) Classification: True Positive (TP)
1541	SPN-817 NCTID: NCT05518578 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: a novel synthetic form of Huperzine A; potentially as an acetylcholinesterase inhibitor and an NMDAR antagonist Area: Nervous System Diseases Indication: Resistant Epilepsy Human Patients: 35 Sponsor: Supernus Pharmaceuticals (SUPN)	Date: 11 Apr 2024 Quarter: Q2'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in motor seizure frequency reduction) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 23 May 2024 Lead Time: 42 days in advance Interpretation: 75% mean focal seizure reduction; 25% TEAE-related discontinuation; high efficacy and high toxicity.	Correct Prediction Conclusion: statistically significant yet commercially insufficient (high toxicity is usually not tolerated for anti-seizure medicine) Classification: True Negative (TN)
1443	Tezepelumab NCTID: NCT04039113 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-TSLP alarmin mAb inhibitor Area: Respiratory Tract Diseases Indication: Chronic Obstructive Pulmonary Disease (COPD) Human Patients: 337 Sponsor: Amgen (AMGN)	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 19 May 2024 Lead Time: 104 days in advance Interpretation: 17% reduced annualized rate of COPD exacerbation compared with placebo (p=0.1042).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
666	ERAS-007 Encorafenib Cetuximab Palbociclib NCTID: NCT05039177 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: ERK1/2 inhibitor Area: Neoplasms Indication: Advanced Gastrointestinal Malignancies Human Patients: 102 Sponsor: Erasca (ERAS)	Date: 1 Dec 2023 Quarter: Q1'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 17 May 2024 Lead Time: 168 days in advance Interpretation: 40% ORR for treatment-naïve cohort which is inferior to the 47.7% cORR achieved by EC+binimetinib (DOI-10.1200/JCO.22.01693); terminated due to low efficacy.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1566	BIIB105 NCTID: NCT04494256 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: anti-ATXN2 ASO Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis and Participants With the ALS Ataxin-2 (ATXN2) Genetic Mutation Human Patients: 99	Date: 23 Apr 2024 Quarter: Q3'24 Batch 3 Technical: FAILURE (statistically insignificant additive clinical benefit to SoC regardless of the CAG repeat expansion level in the ATXN2 gene) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC regardless of the CAG repeat expansion level in the ATXN2 gene)	Readout: 16 May 2024 Lead Time: 23 days in advance Interpretation: no reduction in ALS biomarkers; discontinued.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Biogen / Ionis Pharmaceuticals (BIIB/IONS)			
721	Insulin Efsitora Alfa (LY3209590) Insulin Degludec NCTID: NCT05362058 Phase: Phase 3 Class: Best-In-Class Modality: protein biologic MoA: once-weekly insulin treatment Area: Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Human Patients: 928 Sponsor: Eli Lilly and Company (LLY)	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS (non-inferior)	Readout: 16 May 2024 Lead Time: 537 days in advance Interpretation: -1.34% (efsitora) vs -1.26% (degludec) HbA1C at week 52; non-inferior.	Correct Prediction Conclusion: statistically significant and commercially sufficient (once-weekly is more convenient than SoC's once-daily dosage) Classification: True Positive (TP)
704	LY3209590 NCTID: NCT05462756 Phase: Phase 3 Class: Best-In-Class Modality: protein biologic MoA: once-weekly insulin treatment Area: Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Human Patients: 730 Sponsor: Eli Lilly and Company (LLY)	Date: 21 Nov 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS (non-inferior)	Readout: 16 May 2024 Lead Time: 542 days in advance Interpretation: -1.34% (efsitora) vs -1.26% (degludec) HbA1C at week 52; non-inferior.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1239	CAB-ROR2-ADC PD-1 inhibitor NCTID: NCT03504488 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-ROR2 ADC Area: Neoplasms Indication: TNBC or Head & Neck Cancer (Ph1) and NSCLC or Melanoma (Ph2) Human Patients: 420 Sponsor: BioAtla (BCAB)	Date: 30 Nov 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 May 2024 Lead Time: 166 days in advance Interpretation: 7% ORR for melanoma (vs 21-36% ORR by anti-PD1 + anti-CLTA4 / TIL cell therapy).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1235	Ozuriftamab Vedotin (BA3021) PD-1 inhibitor NCTID: NCT05271604 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-ROR2 ADC Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 80 Sponsor: BioAtla (BCAB)	Date: 3 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 May 2024 Lead Time: 254 days in advance Interpretation: 15% ORR for SCCHN (vs 13-16% ORR by anti-PD1).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1212	RPT193 NCTID: NCT05399368 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral CCR4 inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis	Date: 10 Aug 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 May 2024 Lead Time: 273 days in advance Interpretation: terminated due to clinical holds.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 229 Sponsor: RAPT Therapeutics (RAPT)			
1213	RPT193 NCTID: NCT05935332 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral CCR4 inhibitor Area: Respiratory Tract Diseases Indication: Moderate to Severe T2-high Asthma Human Patients: 38 Sponsor: RAPT Therapeutics (RAPT)	Date: 10 Aug 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 May 2024 Lead Time: 273 days in advance Interpretation: terminated due to clinical holds.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
822	Imsidolimab (ANB019) NCTID: NCT05352893 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-IL36R mAb inhibitor Area: Immune System Diseases Indication: Generalized Pustular Psoriasis Human Patients: 45 Sponsor: AnaptysBio (ANAB)	Date: 27 Dec 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS	Readout: 9 May 2024 Lead Time: 499 days in advance Interpretation: 40% placebo-adjusted GPPPGA score 0/1 (p=0.0131) in GEMINI1.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1386	Imsidolimab (ANB019) NCTID: EUCT2021-001448-90 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-IL36R mAb inhibitor Area: Immune System Diseases Indication: Generalized Pustular Psoriasis Human Patients: 16 Sponsor: AnaptysBio (ANAB)	Date: 17 Dec 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 9 May 2024 Lead Time: 144 days in advance Interpretation: 75% placebo-adjusted GPPPGA score 0/1 maintenance and 63% placebo-adjust flare-free maintenance in GEMINI2.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
812	Vobramitamab Duocarmazine NCTID: NCT05551117 Phase: Phase 2 Class: First-In-Class Modality: ADC MoA: anti-B7-H3 ADC with DUBA payload for lysosomal-protease-cleavage-mediated intracellular release Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer Human Patients: 382 Sponsor: MacroGenics (MGNX)	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with high toxicity) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 May 2024 Lead Time: 67 days in advance Interpretation: 25% ORR (vs 30% ORR for 177Lu-PSMA-617 + SoC in the same setting of 2L mCRPC in phase 3); 93%-95% TEAEs.	Correct Prediction Conclusion: commercially insufficient due to weak efficacy and high toxicity. Classification: True Negative (TN)
669	LYR-210 Sham procedure control Background Therapy NCTID: NCT05219968 Phase: Phase 3 Class: First-In-Class Modality: medical device MoA: long-acting glucocorticoid receptor agonist Area: Respiratory Tract Diseases Indication: Chronic	Date: 15 Dec 2023 Quarter: Q1'24 Batch 11 Technical: partial SUCCESS (statistically significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 6 May 2024 Lead Time: 143 days in advance Interpretation: 3CS primary endpoint not met yet with positive trend (not significant).	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Rhinosinusitis Human Patients: 196 Sponsor: Lyra Therapeutics (LYRA)			
1441	Uproleselan (GMI-1271) NCTID: NCT03616470 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective E-selectin antagonist Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 388 Sponsor: GlycoMimetics (GLYC)	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 Lead Time: 80 days in advance Interpretation: OS primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
744	Setanaxib Pembrolizumab NCTID: NCT05323656 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: NOX1/NOX4 dual inhibitor Area: Neoplasms Indication: Squamous Cell Carcinoma of Head and Neck (SCCHN) Human Patients: 55 Sponsor: Calliditas Therapeutics (CALT)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 Lead Time: 136 days in advance Interpretation: base percentage change in tumor size primary endpoint not met yet PFS/OS secondary endpoints showed positive trends (not significant).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1543	CG0070 n-dodecyl-B-D-maltoside NCTID: NCT04452591 Phase: Phase 3 Class: First-In-Class Modality: oncolytic virus therapy MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene Area: Neoplasms Indication: Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin Human Patients: 190 Sponsor: CG Oncology (CGON)	Date: 15 Apr 2024 Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit with maybe inferior-to-pembrolizumab efficacy in CR/PFS)	Readout: 3 May 2024 Lead Time: 18 days in advance Interpretation: 75.2% CR any time at month 12 (vs 100% CR any time for pembrolizumab at month 12. ASCO 19 KEYNOTE-057); no grade 3 TEAE.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
935	Buntanetap/Posiphen NCTID: NCT05686044 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: neurotoxic protein synthesis inhibitor Area: Nervous System Diseases Indication: Alzheimer Disease Human Patients: 320 Sponsor: Annovis Bio (ANVS)	Date: 24 Mar 2024 Quarter: Q2'24 Batch 13 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 29 Apr 2024 Lead Time: 36 days in advance Interpretation: key efficacy endpoints ADAS-COG11; ADCS-CGIC; ADCS-ADL not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1373	Trastuzumab deruxtecan Capecitabine Paclitaxel Nab-Paclitaxel NCTID: NCT04494425 Phase: Phase 3 Class: First-In-Class	Date: 12 Dec 2023 Quarter: Q1'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS	Readout: 29 Apr 2024 Lead Time: 139 days in advance Interpretation: PFS superior to SoC; OS not mature yet with early positive trend.	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: ADC MoA: anti-HER2 mAb inhibitor conjugated with TOP1 inhibitor Area: Neoplasms Indication: Metastatic Breast Cancer Human Patients: 866 Sponsor: AstraZeneca / Daiichi Sankyo Company (AZN / DSNKY)	(commercially sufficient clinical benefit superior to chemotherapy)		
893	JNJ-40411813 NCTID: NCT04836559 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: mGluR2 PAM Area: Nervous System Diseases Indication: Focal Onset Seizures Human Patients: 110 Sponsor: Johnson & Johnson / Addex Therapeutics (JNJ / ADXN)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 29 Apr 2024 Lead Time: 20 days in advance Interpretation: primary endpoint not met; development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1493	ACR-368 Gemcitabine OncoSignature NCTID: NCT05548296 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: CHEK1/CHEK2 small molecule inhibitor with OncoSignature predictive biomarkers Area: Neoplasms Indication: Ovarian Carcinoma; Endometrial Adenocarcinoma; and Urothelial Carcinoma Human Patients: 390 Sponsor: Acrivon Therapeutics (ACRV)	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in the OncoSignature positive arm) Commercial: SUCCESS (commercially sufficient clinical benefit in the OncoSignature positive monotherapy arm with superior efficacy over the OncoSignature negative combotherapy arm)	Readout: 24 Apr 2024 Lead Time: 52 days in advance Interpretation: 50% ORR for oncosignature positive arm vs 0% Orr for oncosignature negative arm (p=0.0038) vs 42.3% ORR of mirvetuximab soravtansine for patients selected by FOLRalpha; anti-correlation between dosage and efficacy.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1272	Semaglutid NCTID: NCT05064735 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Immune System Diseases Indication: Knee Osteoarthritis Human Patients: 407 Sponsor: Novo Nordisk (NVO)	Date: 9 Oct 2023 Quarter: 2H'23 Batch 22 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 23 Apr 2024 Lead Time: 197 days in advance Interpretation: semaglutide achieved a placebo-adjusted -14.2 WOMAC pain reduction (P<0.001)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1362	NBI-1065845 NCTID: NCT05203341 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: AMPAR PAM Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 183 Sponsor: Neurocrine Biosciences (NBIX)	Date: 30 Nov 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 23 Apr 2024 Lead Time: 145 days in advance Interpretation: significant MADRS for one dose (likely low dose) yet insignificant for another dose (likely high dose); anti-correlation between dosage and efficacy.	Correct Prediction Conclusion: overall statistically insignificant and commercially insufficient Classification: True Negative (TN)
1454	Tavapadon NCTID: NCT04542499 Phase: Phase 3	Date: 14 Feb 2024 Quarter: Q2'24 Batch 4 Technical: FAILURE (statistically	Readout: 18 Apr 2024 Lead Time: 64 days in advance Interpretation: on time 1.7 hours vs	Correct Prediction Conclusion: overall statistically insignificant and commercially

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: small molecule MoA: a selective D1R/D5R partial agonist Area: Nervous System Diseases Indication: Parkinson's Disease Human Patients: 507 Sponsor: AbbVie / Cerevel Therapeutics (ABBV / CERE)	insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	0.6 hours (p<0.0001); key registrational endpoint MDS-UPDRS not met; key registrational endpoint off time reduction met yet fail to reach the minimally clinically meaningful threshold (-1.0 hour and -3.5 points [10.1002/mds.23638.]).	insufficient Classification: True Negative (TN)
1380	SAGE-718 NCTID: NCT05318937 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: NMDAR PAM Area: Nervous System Diseases Indication: Parkinson Disease Cognitive Dysfunction Human Patients: 86 Sponsor: Sage Therapeutics (SAGE)	Date: 15 Dec 2023 Quarter: Q1'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercial sufficient clinical benefit)	Readout: 17 Apr 2024 Lead Time: 124 days in advance Interpretation: WAIS-IV primary efficacy endpoint not met	Missed Prediction Note: due to suboptimal modelling of SAGE718 MoA that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
716	Tirzepatide NCTID: NCT05412004 Phase: Phase 3 Class: First-In-Class Modality: synthetic peptide MoA: GLP1R/GIPR-biased dual agonist Area: Respiratory Tract Diseases Indication: Obstructive Sleep Apnea Human Patients: 469 Sponsor: Eli Lilly and Company (LLY)	Date: 9 Oct 2023 Quarter: 2H'23 Batch 22 Technical: SUCCESS (statistically significant clinical benefit more for GPI2 cohort (tirzepatide + CPAP) than for GPI1 cohort (tirzepatide alone)) Commercial: partial SUCCESS (commercially sufficient clinical benefit for tirzepatide + CPAP more than for tirzepatide alone)	Readout: 17 Apr 2024 Lead Time: 191 days in advance Interpretation: (-30 AHI -63% AHI%) GPI2 Tirzepatide + CPAP > (-27 AHI -55% AHI%) GPI1 Tirzepatide > (33-48% AHI%) GPI2 CPAP [Raveslout and Vries 2011 Sleep] > (-5 AHI -5% AHI%) GPI1 placebo.	Correct Prediction Note: with a minor miss in GPI2 CPAP Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1502	BHV-1300 NCTID: N/A (adapt the NCT06041269 trial design) Phase: Phase 1 Class: First-In-Class Modality: bispecific molecular degrader MoA: bispecific molecule IgG degrader Area: Immune System Diseases Indication: Rheumatoid Arthritis Human Patients: 420 Sponsor: Biohaven (BHAVN)	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-SoC efficacy and non-superior-to-efgartigimod toxicity)	Readout: 17 Apr 2024 Lead Time: 42 days in advance Interpretation: unremarkable IGG data (-37%) inferior to the SoC efgartigimod IGG data (-75%).	Correct Prediction Conclusion: statistically weak and commercially insufficient compared with efgartigimod Classification: True Negative (TN)
352	Lumateperone NCTID: NCT04985942 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: D1R/D2R/D4R/5TH2AR antagonist Area: Mental Disorders Indication: Major Depressive Disorder Human Patients: 485 Sponsor: Intra-Cellular Therapies (ITCI)	Date: 9 Jan 2024 Quarter: Q1'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 16 Apr 2024 Lead Time: 98 days in advance Interpretation: -4.9 placebo-adjusted delta in MADRS score (p<0.0001) & CGI-S (p<0.0001).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1128	GTX-102 NCTID: NCT04259281 Phase: Phase 1 Phase 2	Date: 3 Jan 2024 Quarter: Q1'24 Batch 13 Technical: SUCCESS (statistically	Readout: 15 Apr 2024 Lead Time: 103 days in advance Interpretation: rapid and clinically	Correct Prediction Conclusion: statistically significant and commercially sufficient (no

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: intrathecal UBE3A-AS ASO Area: Nervous System Diseases Indication: Angelman Syndrome Human Patients: 74 Sponsor: Ultragenyx Pharmaceutical (RARE)	significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	significant improvement resulting a total MRDI response of +2.0 (p<0.0001) at Day 170 and +2.0 (p=0.0007) at Day 338.	SoC) Classification: True Positive (TP)
1508	ELVN-001 NCTID: NCT05304377 Phase: Phase 1 a/1b Class: Best-In-Class Modality: small molecule MoA: BCR-ABL1 and T315I selective tyrosine kinase inhibitor Area: Neoplasms Indication: Chronic Myeloid Leukemia Human Patients: 180 Sponsor: Enliven Therapeutics (ELVN)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 11 Apr 2024 Lead Time: 24 days in advance Interpretation: 44% cumulative MRR even for previously treated with asciminib.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1211	FLX475 Pembrolizumab NCTID: NCT03674567 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: CCR4 antagonist Area: Neoplasms Indication: Advanced Cancer Human Patients: 323 Sponsor: RAPT Therapeutics (RAPT)	Date: 10 Aug 2023 Quarter: 2H'23 Batch 12 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 10 Apr 2024 Lead Time: 244 days in advance Interpretation: 15.6% ORR (vs 27.3% ORR by pembrolizumab alone as 2L for advanced HNSCC in KEYNOTE-048.	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1268	ALKS 2680 NCTID: ISRCTN98204977 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: HCRTR2 agonist Area: Nervous System Diseases Indication: Narcolepsy Human Patients: 147 Sponsor: Alkermes (ALKS)	Date: 5 Oct 2023 Quarter: 2H'23 Batch 21 Technical: partial SUCCESS (statistically significant clinical benefit in efficacy); partial FAILURE (statistically insignificant clinical benefit in toxicity worse for NT1 than for NT2) Commercial: FAILURE (commercially insufficient clinical benefit due to on-target toxicity non-superior to TAK994 or JZP441)	Readout: 10 Apr 2024 Lead Time: 188 days in advance Interpretation: safe and effective; advance to NT1/NT2 only; not IH	Overall Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Negative (TN)
1137	Ac225-PSMA I&T NCTID: NCT05219500 Phase: Phase 2 Class: First-In-Class Modality: radioligand therapy MoA: anti-PSMA mAb conjugated to alpha particle-emitting cytotoxic isotope Actinium-225 Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer (mCRPC) Human Patients: 115 Sponsor: Fusion Pharmaceuticals (FUSN)	Date: 1 Dec 2023 Quarter: Q1'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient clinical benefit non-inferior and non-superior to SoC)	Readout: 9 Apr 2024 Lead Time: 130 days in advance Interpretation: 50% PSA50 33% ORR (vs 57.6% PSA50 and 50.7% ORR of Pluvicto or 42% ORR PSA50 and 60% ORR of PNT2002 in advanced mCRPC).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Positive (TP)
1482	VIP236	Date: 26 Feb 2024	Readout: 8 Apr 2024	Missed Prediction

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05712889 Phase: Phase 1 Class: First-In-Class Modality: small molecule drug conjugate (SMDC) MoA: alpha5beta3-integrin-specific SMDC with NE-cleavage-mediated release of CPT payload Area: Neoplasms Indication: Advanced Cancer Human Patients: 24 Sponsor: Vincerx Pharma (VINC)	Quarter: Q2'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in PFS/OS/ORR) Commercial: SUCCESS (commercially sufficient clinical benefit)	Lead Time: 42 days in advance Interpretation: safer yet with 0% ORR.	Note: due to suboptimal modelling of linker that has been permanently corrected Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
870	INZ-701 NCTID: NCT05030831 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: soluble recombinant ENPP1 enzyme Area: Cardiovascular Diseases Indication: ABCC6 Deficiency Causing Pseudoxanthoma Elasticum (PXE) Human Patients: 10 Sponsor: Inozyme Pharma (INZY)	Date: 16 Jan 2024 Quarter: Q1'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 8 Apr 2024 Lead Time: 83 days in advance Interpretation: safe with clinical improvement in multiple exploratory efficacy endpoints.	Correct Prediction Conclusion: statistically significant (phase 1/2) and commercially TBD Classification: True Positive (TP)
788	ARO-APOC3 NCTID: NCT04720534 Phase: Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: siRNA-GalNAc conjugate that suppresses APOC3 mRNA Area: Nutritional and Metabolic Diseases Indication: Severe Hypertriglyceridemia Human Patients: 229 Sponsor: Arrowhead Pharmaceuticals (ARWR)	Date: 14 Feb 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 7 Apr 2024 Lead Time: 53 days in advance Interpretation: 86% triglyceride reduction superior to 30-50% achieved by SoC (Fibrates).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1512	Semaglutide NCTID: NCT04916470 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Heart Failure With Preserved Ejection Fraction (HFpEF) and Diabetes Mellitus Type 2 Human Patients: 610 Sponsor: Novo Nordisk (NVO)	Date: 23 Mar 2024 Quarter: Q2'24 Batch 13 Technical: FAILURE (statistically insignificant additive clinical benefit in KCCQ and 6MWD as an adjunctive therapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in KCCQ and 6MWD as an adjunctive therapy)	Readout: 7 Apr 2024 Lead Time: 15 days in advance Interpretation: 7.3 point improvement in KCCQ-CSS (5 is the minimum clinically meaningful standard) & 14.3m improvement in 6MWD vs 80m as sufficient for a quality-of-life improvement (Morbach et al. 2024 Clinical Research In Cardiology); 25m as clinically meaningful improvement (Jain et al. Arnold 2021 Circulation Heart Failure).	Overall Correct Prediction Conclusion: statistically significant (placebo) yet commercially insufficient (small 6MWD; Novo Nordisk decided not to file an NDA for marketing approval) Classification: True Negative (TN)
1376	Zilebesiran Olmesartan Amlodipine Indapamide NCTID: NCT05103332 Phase: Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense	Date: 15 Dec 2023 Quarter: Q1'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 7 Apr 2024 Lead Time: 114 days in advance Interpretation: statistically insignificant changes in 24-Hour Mean SBP for the SoC olmesartan ((p=0.036 by phase 3 standard; Paz et so. Coll-de-Tuero 2016 Medicine;	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	oligonucleotide MoA: anti-AGT siRNA Area: Cardiovascular Diseases Indication: Hypertension Human Patients: 672 Sponsor: Alnylam Pharmaceuticals (ALNY)		Chrysant et Al. Robinson 2003 J of Human Hypertension) in both primary/secondary endpoints.	
1345	KPL-404 NCTID: NCT05198310 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CD40 mAb inhibitor Area: Immune System Diseases Indication: Rheumatoid Arthritis Human Patients: 145 Sponsor: Kiniksa Pharmaceuticals (KNSA)	Date: 26 Nov 2023 Quarter: Q1'24 Batch 7 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 2 Apr 2024 Lead Time: 128 days in advance Interpretation: DAS28-CRP primary endpoint not met for cohort 3 and cohort 4.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1344	GRT-C901 GRT-R902 Atezolizumab Ipilimumab Fluoropyrimidine plus leucovorin Bevacizumab NCTID: NCT05141721 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: cancer vaccine MoA: modified-chimpanzee-adenoviral patient-specific neoantigen vaccine Area: Neoplasms Indication: Metastatic Colorectal Cancer Human Patients: 700 Sponsor: Gritstone bio (GRTS)	Date: 26 Nov 2023 Quarter: Q1'24 Batch 7 Technical: SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 1 Apr 2024 Lead Time: 127 days in advance Interpretation: weak PFS trend that's not statistically significant yet.	Correct Prediction Conclusion: statistically significant yet commercially insufficient (weak efficacy) Classification: True Negative (TN)
1307	CT-0508 Pembrolizumab NCTID: NCT04660929 Phase: Phase 1 Class: First-In-Class Modality: CAR-Macrophage therapy MoA: anti-HER2 CAR-M1 Area: Neoplasms Indication: HER2-positive Adenocarcinoma Bile Duct Cancer Biliary Tract Cancer Bladder Cancer Breast CancerBreast Neoplasm Carcinoma Ductal Carcinoma Hepatocellular Cancer Lung Cancer Non-Small Cell Carcinoma Ovarian Epithelial Carcinoma Small Cell Carcinoma Squamous Carcinoma Transitional Cell Colorectal Cancer Esophagogastric Junction Neoplasms Inflammatory Breast Cancer Stomach Neoplasms Malignant Neoplasms Ovarian Neoplasms Pancreatic Cancer HER2-positive Solid Tumors HER2-positive Breast Cancer HER2-positive Gastric Cancer HER-2 Protein Overexpression HER-2 Gene Amplification Prostate Cancer Head and Neck Cancer Endometrial Cancer Lung Cancer Small Cel Human Patients: 48	Date: 31 Oct 2023 Quarter: 2H'23 Batch 26 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 1 Apr 2024 Lead Time: 153 days in advance Interpretation: safe yet terminated due to insufficient efficacy.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Carisma Therapeutics (CARM)			
845	EQ001 (Itolizumab) NCTID: NCT04128579 Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CD6 mAb inhibitor Area: Immune System Diseases Indication: Systemic Lupus Erythematosus With or Without Active Proliferative Nephritis Human Patients: 55 Sponsor: Equillium (EQ)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant yet moderate clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit)	Readout: 1 Apr 2024 Lead Time: 43 days in advance Interpretation: 80% ORR in UPCR.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1022	DISC-1459 NCTID: ACTRN12622000799752 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: GLYT1 small molecule inhibitor Area: Digestive System Diseases Indication: Erythropoietic Protoporphyrria (EEP) Human Patients: 22 Sponsor: Disc Medicine (IRON)	Date: 24 Apr 2023 Quarter: Q2'23 Batch 18 Technical: partial SUCCESS (statistically significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 1 Apr 2024 Lead Time: 343 days in advance Interpretation: primary endpoint met yet key secondary endpoint (light tolerance) not met.	Overall Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient. Original correct prospective prediction No.1022 in Q2'23; then modified to the false prediction misled by later released preliminary data. Classification: True Negative (TN)
466	Apraglutide NCTID: NCT05415410 Phase: Phase 2 Class: Best-In-Class Modality: peptide drug MoA: GLP2R agonist Area: Immune System Diseases Indication: Graft Versus Host Disease (GVHD). Human Patients: 31 Sponsor: Ironwood Pharmaceuticals (IRWD)	Date: 5 Jan 2024 Quarter: Q1'24 Batch 17 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 28 Mar 2024 Lead Time: 83 days in advance Interpretation: phase 2a safety primary endpoint met and showed sustained response.	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
984	NovoTTF-200M device Best Standard of Care NCTID: NCT02831959 Phase: Phase 3 Class: First-In-Class Modality: medical device MoA: a device delivering low-intensity, wave-like alternating electric fields to the location of the tumor Area: Neoplasms Indication: Brain Metastases From Non-small Cell Lung Cancer (NSCLC) Human Patients: 270 Sponsor: NovoCure (NVCR)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 12 Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 27 Mar 2024 Lead Time: 96 days in advance Interpretation: 21.9month vs 11.3month time to intracranial progression (p=0.016) OS secondary endpoint not met.	Correct Prediction Conclusion: statistically significant yet commercially insufficient (no OS benefit) Classification: True Negative (TN)
1056	serdexmethylphenidate (SDX) NCTID: NCT05668754 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: norepinephrine/dopamine reuptake inhibitors Area: Nervous System Diseases	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 26 Mar 2024 Lead Time: 41 days in advance Interpretation: primary safety endpoint met and secondary efficacy endpoints meaningful.	Correct Prediction Conclusion: statistically significant and commercially sufficient to advance to phase 3 Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Idiopathic Hypersomnia Human Patients: 50 Sponsor: Zevra Therapeutics (ZVRA)			
476	VK2735 NCTID: NCT05204237 Phase: Phase 1 Class: Best-In-Class Modality: peptide drug MoA: GLP1R/GIPR-biased dual agonist Area: Nutritional and Metabolic Diseases Indication: Weight Loss NASH Human Patients: 136 Sponsor: Viking Therapeutics (VKTX)	Date: 16 Oct 2023 Quarter: Q1'24 Batch 4 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to GSK1289 and orforglipron)	Readout: 26 Mar 2024 Lead Time: 162 days in advance Interpretation: 5.3% from baseline and 3.3% placebo-adjust weight reduction at 4 weeks vs 3% from baseline and 2% placebo-adjusted weight reduction for tirzapatide.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1397	STAR-0215 NCTID: NCT05695248 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: monoclonal antibody (mAb) MoA: YTE-modified anti-kallikrein mAb inhibitor Area: Cardiovascular Diseases Indication: Hereditary Angioedema Human Patients: 28 Sponsor: Astria Therapeutics (ATXS)	Date: 21 Dec 2023 Quarter: Q1'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-lanadelumab efficacy and durability)	Readout: 25 Mar 2024 Lead Time: 95 days in advance Interpretation: -93% mean monthly HAE attacks vs -85% by PHVS's deucricitab; -92%-100% moderate to severe HAE attacks vs 83% by Takeda's lanadelumab.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
896	AXS-12 (reboxetine) NCTID: NCT05059223 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: selectively inhibitor of the reuptake of norepinephrine Area: Nervous System Diseases Indication: Narcolepsy Human Patients: 90 Sponsor: Axsome Therapeutics (AXSM)	Date: 1 Dec 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 25 Mar 2024 Lead Time: 115 days in advance Interpretation: 83% cataplexy attack reduction achieved by AXS12; superior to 49-69% cataplexy attack reduction achieved by the SoC Sodium oxybate (doi.org/10.1016/j.sleep.2003.11.002) primary and secondary endpoints met.	Correct Prediction Conclusion: statistical significant and commercially sufficient Classification: True Positive (TP)
1058	Paltusotine NCTID: NCT05192382 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: SST2R agonist Area: Musculoskeletal Diseases Indication: Acromegaly Human Patients: 111 Sponsor: Crinetics Pharmaceuticals (CRNX)	Date: 14 Aug 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to octreotide)	Readout: 19 Mar 2024 Lead Time: 218 days in advance Interpretation: 56% patients achieved IGF1 level < 1.0% and -2.67 ASD score; superior to the SoC octreotide LAR achieved 23.3% patients achieved IGF1 level < 1.0% and -2.67 ASD score.	Correct Prediction Conclusion: statistical significant and commercially sufficient Classification: True Positive (TP)
1370	Lanifibranor (IVA337) Placebo Empagliflozin NCTID: NCT05232071 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: It is a pan-PPAR agonist Area: Nutritional and Metabolic	Date: 2 Dec 2023 Quarter: Q1'24 Batch 9 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit for lanifibranor + empagliflozin) Commercial: FAILURE (commercially	Readout: 18 Mar 2024 Lead Time: 107 days in advance Interpretation: -1.15% & -1.6% HbA1c (mono and combo) at week 24; inferior to the SoC tirzapatide -1.6-2.4% HbA1c at week 26.	Correct Prediction Conclusion: statistical significant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Diseaseses Indication: NASH and Type 2 Diabetes Mellitus Human Patients: 42 Sponsor: Inventiva Pharma (IVA)	insufficient clinical benefit for lanifibranor + empagliflozin; inferior to tirzepatide)		
911	Tildacerfont NCTID: NCT04457336 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral small molecule CRF1R antagonist Area: Urogenital Diseases Indication: Congenital Adrenal Hyperplasia Human Patients: 96 Sponsor: Spruce Biosciences (SPRB)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 13 Mar 2024 Lead Time: 104 days in advance Interpretation: primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1059	Paltusotine NCTID: NCT05361668 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: SST2R agonist Area: Neoplasms Indication: Carcinoid Syndrome Human Patients: 36 Sponsor: Crinetics Pharmaceuticals (CRNX)	Date: 14 Aug 2023 Quarter: 2H'23 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to octreotide)	Readout: 12 Mar 2024 Lead Time: 211 days in advance Interpretation: 63% reduction flushing frequency and 60% reduction in bowel movement frequency p<0.0001; both superior to the 20-35% reduction in flushing and bowel movement achieved by SoC (DOI- 10.1093/annonc/mdy293.007).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1346	Pimavanserin NCTID: NCT04531982 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: 5HT2AR/5HT2CR antagonist Area: Nervous System Diseases Indication: Schizophrenia Human Patients: 454 Sponsor: Acadia Pharmaceuticals (ACAD)	Date: 27 Nov 2023 Quarter: Q1'24 Batch 6 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit non-inferior to KarXT)	Readout: 11 Mar 2024 Lead Time: 105 days in advance Interpretation: primary endpoint not met.	Missed Prediction Note: due to suboptimal modeling of drug MoA that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
717	Lebrikizumab (LY3650150) NCTID: NCT05372419 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody (mAb) MoA: IL-13 mAb inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis and Skin of Color Human Patients: 80 Sponsor: Eli Lilly and Company (LLY)	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS	Readout: 11 Mar 2024 Lead Time: 471 days in advance Interpretation: 68% EASI75 and 46% EASI90 55% itch reduction and 39% clear of skin; which is superior to 49% EASI75 achieved by dupilumab.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1185	Izokibep NCTID: NCT05623345 Phase: Phase 2 Phase 3 Class: Best-In-Class Modality: small protein scaffold-based biologic MoA: IL-17A Inhibitor Area: Musculoskeletal Diseases	Date: 20 Nov 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially insufficient clinical benefit with	Readout: 11 Mar 2024 Lead Time: 112 days in advance Interpretation: 28% placebo-controlled ACR50 response at wk 16 with 2.5% discontinuation rate; which is inferior to 36% placebo-controlled ACR50 response at wk 16 and 0.4% discontinuation	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

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#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Psoriatic Arthritis Human Patients: 351 Sponsor: Acelyrin (SLRN)	non-superior-to-bimekizumab efficacy and inferior-to-bimekizumab toxicity)	rate; achieved by bimekizumab (DOI-10.1016/S0140-6736(22)02303-0).	
342	AMX0035 NCTID: NCT05021536 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: sodium phenylbutyrate + taurursodiol Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis Human Patients: 600 Sponsor: Amylyx Pharmaceuticals (AMLX)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 8 Mar 2024 Lead Time: 19 days in advance Interpretation: endpoints not met.	Missed Prediction Note: due to suboptimal modelling of ALS that has been permanently corrected. Conclusion: statistical insignificant and commercially insufficient Classification: False Positive (FP)
1047	BMF-219 NCTID: NCT05731544 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: oral small molecule MENIN inhibitor Area: Nutritional and Metabolic Diseases Indication: Type 2 Diabetes Mellitus Human Patients: 414 Sponsor: Biomea Fusion (BMEA)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit for T2DM patients)	Readout: 6 Mar 2024 Lead Time: 6 days in advance Interpretation: -0.4% to -1.4% HbA1c at week 26; which is inferior to tirzepatide's -1.6 to -2.4% HbA1c at week 26; full clinical hold due to hepatotoxicity	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
999	AOC 1001 NCTID: NCT05027269 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: anti-DMPK siRNA Area: Musculoskeletal Diseases Indication: Myotonic Dystrophy Type 1 (DM1) Human Patients: 38 Sponsor: Avidity Biosciences (RNA)	Date: 22 Apr 2023 Quarter: Q2'23 Batch 16 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 4 Mar 2024 Lead Time: 317 days in advance Interpretation: no change in toxicity or efficacy in OLE	Correct Prediction Conclusion: statistical insignificant and commercially insufficient Classification: True Negative (TN)
1431	PQ912 NCTID: NCT04498650 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: QPCT/QPCTL inhibitor Area: Nervous System Diseases Indication: Early Alzheimers Disease Mild Cognitive Impairment Due to AD Human Patients: 259 Sponsor: Vivoryon Therapeutics (VVY)	Date: 20 Jan 2024 Quarter: Q1'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to donanemab or lecanemab)	Readout: 4 Mar 2024 Lead Time: 44 days in advance Interpretation: primary/secondary endpoint not met.	Overall Correct Prediction Conclusion: statistical insignificant and commercially insufficient Classification: True Negative (TN)
463	Apraglutide NCTID: NCT04627025 Phase: Phase 3 Class: Best-In-Class Modality: peptide drug MoA: GLP2R agonist Area: Digestive System Diseases	Date: 5 Jan 2024 Quarter: Q1'24 Batch 17 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical	Readout: 29 Feb 2024 Lead Time: 55 days in advance Interpretation: 13% placebo-adjusted actual weekly PS volume change (p=0.001) & at least 1 day/week (p=0.04) at week 24 vs 17% actual weekly PS volume change (p<0.001)	Overall Correct Prediction Conclusion: statistically significant; once-weekly apraglutide commercially sufficient non-inferior to once-daily teduglutide Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

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#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Short Bowel Syndrome with Intestinal Failure (SBS-IF) Human Patients: 164 Sponsor: Ironwood Pharmaceuticals (IRWD)	benefit)	for once-daily teduglutide; effective for stoma population but not effective for colon-in-continuity population with less intestine resection.	
1290	VK2735 NCTID: NCT06068946 Phase: Phase 2 Class: Best-In-Class Modality: synthetic peptide MoA: GLP1R/GIPR-biased dual agonist Area: Nutritional and Metabolic Diseases Indication: Weight Loss Human Patients: 176 Sponsor: Viking Therapeutics (VKTX)	Date: 15 Oct 2023 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to GSKR1289 and orforglipron)	Readout: 27 Feb 2024 Lead Time: 135 days in advance Interpretation: 13.1% placebo-adjusted weight loss at week 13 vs 7% of tirzepatide at week 13; no plateau.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1336	ARS-1 NCTID: NCT05496465 Phase: Phase 2 Class: Best-In-Class Modality: medical device MoA: epinephrine spray Area: Skin and Connective Tissue Diseases Indication: Urticaria Human Patients: 24 Sponsor: ARS Pharmaceuticals (SPRY)	Date: 20 Nov 2023 Quarter: 2H'23 Batch 30 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 26 Feb 2024 Lead Time: 98 days in advance Interpretation: primary endpoint met with p<0.05 that's not comparable with CDX0159 that achieved 40.6% placebo-adjusted CR.	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)
1341	SAR443820 NCTID: NCT05237284 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: RIPK1 inhibitor Area: Nervous System Diseases Indication: Amyotrophic Lateral Sclerosis Human Patients: 305 Sponsor: Denali Therapeutics / Sanofi (DNL/SNY)	Date: 21 Nov 2023 Quarter: Q1'24 Batch 7 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 16 Feb 2024 Lead Time: 87 days in advance Interpretation: primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1068	KVD900 NCTID: NCT05259917 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: plasma kallikrein inhibitor Area: Cardiovascular Diseases Indication: Hereditary Angioedema Human Patients: 136 Sponsor: KalVista Pharmaceuticals (KALV)	Date: 25 May 2023 Quarter: 2H'23 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (Commercially sufficient clinical benefit non-inferior to lanadelumab)	Readout: 13 Feb 2024 Lead Time: 264 days in advance Interpretation: met all primary and secondary endpoints.	Correct Prediction Conclusion: statistically significant and commercially sufficient as a non-inferior oral on-demand treatment Classification: True Positive (TP)
1006	4D-310 NCTID: NCT05629559 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: AAV GLA gene therapy Area: Nervous System Diseases Indication: Fabry Disease	Date: 2 Dec 2023 Quarter: Q1'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Feb 2024 Lead Time: 72 days in advance Interpretation: weak efficacy in cardiac endpoints (minimal clinically important difference (MCID) no key renal endpoints with previous clinical hold due to toxicity.	Correct Prediction Conclusion: more likely to be statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 18 Sponsor: 4D Molecular Therapeutics (FDMT)			
1409	CTI-1601 NCTID: NCT05579691 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: TAT-delivered FXN recombinant fusion protein Area: Nervous System Diseases Indication: Friedreich Ataxia Human Patients: 28 Sponsor: Larimar Therapeutics (LRMR)	Date: 7 Jan 2024 Quarter: Q1'24 Batch 14 Technical: partial SUCCESS (statistically significant yet weak clinical benefit due to TAT delivery) Commercial: FAILURE (commercially insufficient clinical benefit inferior to omaveloxolone)	Readout: 12 Feb 2024 Lead Time: 36 days in advance Interpretation: insignificant FXN levels	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)
709	Tirzepatide (LY3298176) NCTID: NCT04166773 Phase: Phase 2 Class: First-In-Class Modality: synthetic peptide MoA: GLP1R/GIPR-biased dual agonist Area: Nutritional and Metabolic Diseases Indication: Nonalcoholic Steatohepatitis (NASH) Human Patients: 196 Sponsor: Eli Lilly and Company (LLY)	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS	Readout: 6 Feb 2024 Lead Time: 437 days in advance Interpretation: 61% placebo-adjusted absence of NASH with no worsening of fibrosis; which is superior to 16-20% achieved by the SoC resmetrom	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1276	VX-121/TEZ/D-IVA ELX/TEZ/IVA IVA NCTID: NCT05033080 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: CFTR modulator Area: Respiratory Tract Diseases Indication: Cystic Fibrosis Human Patients: 435 Sponsor: Vertex Pharmaceuticals (VRTX)	Date: 3 Dec 2023 Quarter: Q1'24 Batch 22 Technical: SUCCESS (statistically significant clinical benefit non-inferior and non-superior to Trikafta) Commercial: SUCCESS (commercially sufficient clinical benefit with once-daily dosing regimen)	Readout: 5 Feb 2024 Lead Time: 64 days in advance Interpretation: all primary and key secondary endpoints of non-inferiority are met	Correct Prediction Conclusion: statistically significant and commercially sufficient (once-daily) Classification: True Positive (TP)
1277	VX-121/TEZ/D-IVA ELX/TEZ/IVA IVA NCTID: NCT05076149 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: CFTR modulator Area: Respiratory Tract Diseases Indication: Cystic Fibrosis Human Patients: 597 Sponsor: Vertex Pharmaceuticals (VRTX)	Date: 3 Dec 2023 Quarter: Q1'24 Batch 9 Technical: SUCCESS (statistically significant clinical benefit non-inferior and non-superior to Trikafta) Commercial: SUCCESS (commercially sufficient clinical benefit with once-daily dosing regimen)	Readout: 5 Feb 2024 Lead Time: 64 days in advance Interpretation: all primary and key secondary endpoints of non-inferiority are met	Correct Prediction Conclusion: statistically significant and commercially sufficient (once-daily) Classification: True Positive (TP)
1278	VX-121/TEZ/D-IVA NCTID: NCT05422222 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: CFTR modulator Area: Respiratory Tract Diseases Indication: Cystic Fibrosis Human Patients: 210	Date: 12 Oct 2023 Quarter: Q1'24 Batch 9 Technical: SUCCESS (statistically significant clinical benefit non-inferior and non-superior to Trikafta) Commercial: SUCCESS (commercially sufficient clinical benefit with once-daily dosing regimen)	Readout: 5 Feb 2024 Lead Time: 116 days in advance Interpretation: all primary and key secondary endpoints of non-inferiority are met.	Correct Prediction Conclusion: statistically significant and commercially sufficient (once-daily) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Vertex Pharmaceuticals (VRTX)			
1347	Ziftomenib NCTID: NCT04067336 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Menin-MLL1 inhibitor Area: Neoplasms Indication: Relapsed or Refractory Acute Myeloid Leukemia Human Patients: 199 Sponsor: Kura Oncology (KURA)	Date: 28 Nov 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 30 Jan 2024 Lead Time: 63 days in advance Interpretation: 65% ORR with 70% Top CR; non-superior to chemo's 60%-70% CR.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1284	VX-548 NCTID: NCT05558410 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: Nav1.8 inhibitor Area: Nervous System Diseases Indication: Acute Pain After an Abdominoplasty Human Patients: 1118 Sponsor: Vertex Pharmaceuticals (VRTX)	Date: 12 Oct 2023 Quarter: 2H'23 Batch 23 Technical: SUCCESS (statistically significant clinical benefit compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit due to non-superior-to-HB/APAP efficacy and inferior-to-HB/APAP toxicity leading to significant risk of post-marketing withdrawal)	Readout: 30 Jan 2024 Lead Time: 110 days in advance Interpretation: statistically significant than placebo; non-superior to HB/APAP in all endpoints.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1285	VX-548 HB/APAP NCTID: NCT05553366 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: Nav1.8 inhibitor Area: Nervous System Diseases Indication: Acute Pain After a Bunionectionomy Human Patients: 1075 Sponsor: Vertex Pharmaceuticals (VRTX)	Date: 12 Oct 2023 Quarter: 2H'23 Batch 23 Technical: SUCCESS (statistically significant clinical benefit compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit due to superior-to-HB/APAP efficacy and non-inferior-to-HB/APAP toxicity)	Readout: 30 Jan 2024 Lead Time: 110 days in advance Interpretation: statistically significant than placebo; VX-548 is superior to HB/APAP inSPID48 for bunionectionomy (P=0.0016) and non-superior in other endpoints.	Overall Correct Prediction Conclusion: statistically significant and overall commercially sufficient Classification: True Positive (TP)
1408	Sacituzumab Govitecan-hzyi (SG) Docetaxel NCTID: NCT05089734 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload for lysosomal-degradation-mediated intracellular release Area: Neoplasms Indication: Non-Small Cell Lung Cancer (NSCLC) Human Patients: 603 Sponsor: Gilead Sciences (GILD)	Date: 5 Jan 2024 Quarter: Q1'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak additional clinical benefit in OS compared with docetaxel) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 22 Jan 2024 Lead Time: 17 days in advance Interpretation: OS primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercial insufficient Classification: True Negative (TN)
1400	Donidalorsen (ISIS 721744 or IONIS-PKK-LRx) NCTID: NCT05139810 Phase: Phase 3 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: GalNAc3-conjugated anti-prekallikrein ASO Area: Cardiovascular Diseases	Date: 3 Jan 2024 Quarter: Q1'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit non-superior non-inferior to deucritibant)	Readout: 22 Jan 2024 Lead Time: 19 days in advance Interpretation: primary and secondary endpoints met with 87% lower attack rate vs 85% lower attack rate achieved by deucritibant.	Correct Prediction Conclusion: statistically significant and commercial sufficient (no approved drug for this MoA). Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Hereditary Angioedema Human Patients: 91 Sponsor: Ionis Pharmaceuticals (IONS)			
508	AB680 Zimberelimab Nab-paclitaxel Gemcitabine NCTID: NCT04104672 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: CD73 inhibitor Area: Neoplasms Indication: Advanced Pancreatic Cancer Human Patients: 195 Sponsor: Arcus Biosciences (RCUS)	Date: 18 Jun 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 16 Jan 2024 Lead Time: 212 days in advance Interpretation: ORR/OS/PFS endpoints not met for both Q+ SoC and QZ+ SoC with mOS trend (15 vs 12 months for SoC).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1089	Liretelimab (AK002) NCTID: NCT05155085 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: SIGLEC8 mAb inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis Human Patients: 131 Sponsor: Allakos (ALLK)	Date: 6 Jun 2023 Quarter: 2H'23 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit for refractory patients superior to omalizumab)	Readout: 16 Jan 2024 Lead Time: 224 days in advance Interpretation: primary endpoint not met.	Missed Prediction Note: due to suboptimal drug MoA modelling that has been permanently corrected. Conclusion: statistically insignificant commercially insufficient Classification: False Positive (FP)
770	ATI-1777 NCTID: NCT05432596 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: JAK1/JAK3 inhibitor Area: Skin and Connective Tissue Diseases Indication: Atopic Dermatitis Human Patients: 250 Sponsor: Aclaris Therapeutics (ACRS)	Date: 7 Jan 2024 Quarter: Q1'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit due to crowded market)	Readout: 10 Jan 2024 Lead Time: 3 days in advance Interpretation: ATI1777 achieved 70% EASI with 11% delta vs dupilumab that achieved 72-80% EASI with 40% delta.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1279	ORIC-944 NCTID: NCT05413421 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: PRC2 inhibitor Area: Neoplasms Indication: Metastatic Prostate Cancer Human Patients: 42 Sponsor: ORIC Pharmaceuticals (ORIC)	Date: 11 Oct 2023 Quarter: Q1'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 8 Jan 2024 Lead Time: 89 days in advance Interpretation: no efficacy data on key secondary endpoints ORR/PFS yet advancing combination therapy forward only (widely accepted strong sign of weak efficacy).	Correct Prediction Conclusion: commercial insufficient Classification: True Negative (TN)
1271	PRX012 NCTID: TBD Phase: Phase 1 Class: Best-In-Class Modality: monoclonal antibody (mAb) MoA: amyloid beta mAb inhibitor Area: Nervous System Diseases Indication: Alzheimer Disease	Date: 6 Oct 2023 Quarter: 2H'23 Batch 21 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to both donanemab and lecanemab)	Readout: 8 Jan 2024 Lead Time: 94 days in advance Interpretation: encouraging amyloid beta reduction without numbers (widely accepted strong sign of weak efficacy).	Correct Prediction Conclusion: commercial insufficient inferior to both donanemab and lecanemab Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 100 Sponsor: Prothena Corporation (PRTA)			
961	ARGX-117 NCTID: NCT05225675 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: C2 mAb inhibitor Area: Nervous System Diseases Indication: Multifocal Motor Neuropathy Human Patients: 54 Sponsor: argenx (ARGX)	Date: 30 Nov 2023 Quarter: Q1'24 Batch 4 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 8 Jan 2024 Lead Time: 39 days in advance Interpretation: 91% placebo-adjusted reduction in the need for IVIg rescue.	Correct Prediction Conclusion: statistically significant and commercially sufficient (no approved SoC for reducing IVIg rescue) Classification: True Positive (TP)
1312	AT-001 NCTID: NCT04083339 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: Aldose Reductase inhibitor Area: Cardiovascular Diseases Indication: Diabetic Cardiomyopathy Human Patients: 675 Sponsor: Applied Therapeutics (APLT)	Date: 2 Nov 2023 Quarter: 2H'23 Batch 27 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 8 Jan 2024 Lead Time: 67 days in advance Interpretation: primary efficacy endpoint peak VO2 not met.	Correct Prediction Conclusion: statistically insignificant and commercial insufficient Classification: True Negative (TN)
1254	DYNE-101 NCTID: NCT05481879 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small interfering RNA (siRNA) antisense oligonucleotide MoA: anti-DMPK siRNA Area: Musculoskeletal Diseases Indication: Myotonic Dystrophy Type 1 Human Patients: 72 Sponsor: Dyne Therapeutics (DYN)	Date: 21 Nov 2023 Quarter: Q1'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in 10MWR)	Readout: 3 Jan 2024 Lead Time: 43 days in advance Interpretation: 40% DMPK knowddown and 3.8 second benefit in myotonia at 6 months; no report of key 10MWR functional endpoints.	Correct Prediction Note: correct technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1259	LP352 NCTID: NCT05364021 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: 5HT2C superagonist Area: Nervous System Diseases Indication: Developmental and Epileptic Encephalopathies Human Patients: 52 Sponsor: Longboard Pharmaceuticals (LBPH)	Date: 2 Oct 2023 Quarter: 2H'23 Batch 19 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 2 Jan 2024 Lead Time: 92 days in advance Interpretation: 32.5% motor seizure frequency reduction compared with placebo.	Missed Prediction Note: due to suboptimal MoA modelling that has been permanently corrected. Conclusion: statistically significant and commercially sufficient Classification: False Negative (FN)
927	Aficamten (CK-3773274) NCTID: NCT05186818 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: cardiac myosin inhibitor Area: Cardiovascular Diseases Indication: Obstructive Hypertrophic Cardiomyopathy (oHCM)	Date: 21 Aug 2023 Quarter: 2H'23 Batch 16 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to metoprolol succinate)	Readout: 27 Dec 2023 Lead Time: 128 days in advance Interpretation: primary endpoint met with 1.74/mL/kg/min placebo-adjusted pVO2 improvement superior to the previous best treatment metoprolol succinate; and all endpoints met with high stitistical significane (p<0.0001) even for patients who have received background beta-blockers.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (552 of 604 trials)

Filtered view:

Oncology

Immunology

Metabolic

Neurology

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 282 Sponsor: Cytokinetics (CYTK)			
963	Efgartigimod NCTID: NCT04598451 Phase: Phase 3 Class: First-In-Class Modality: antibody fragment biologic MoA: anti-FcRn antibody fragment Area: Skin and Connective Tissue Diseases Indication: Pemphigus Human Patients: 222 Sponsor: argenx (ARGX)	Date: 4 Jul 2023 Quarter: 2H'23 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 20 Dec 2023 Lead Time: 169 days in advance Interpretation: primary or secondary endpoints not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
973	Semaglutide NCTID: NCT03574597 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: GLP1R agonist Area: Cardiovascular Diseases and Nutritional and Metabolic Diseases Indication: Cardiovascular risk in obesity patients Human Patients: 17604 Sponsor: Novo Nordisk (NVO)	Date: 20 May 2023 Quarter: 1H'23 Batch Update Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 8 Aug 2023 Lead Time: 80 days in advance Interpretation: semaglutide + SoC achieved 20% reduction in MACE-3 compared with placebo + SoC (6.5% vs 8.0%; HR = 0.80; P < 0.001) (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Appendix: Statistical Methodology & Glossary

KPI FORMULAS

Accuracy

$$(TP + TN) / (TP + TN + FP + FN)$$

Precision (PPV)

$$TP / (TP + FP)$$

NPV

$$TN / (TN + FN)$$

F1-Score

$$2 \times TP / (2 \times TP + FP + FN)$$

DOR

$$(TP \times TN) / (FP \times FN)$$

Sensitivity

$$TP / (TP + FN)$$

Specificity

$$TN / (TN + FP)$$

GLOSSARY

Ex-Ante / Prospective

Prediction issued before outcome is known; timestamped proof

TP

True Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, confirmed by clinical readout

TN

True Negative — predicted non-blockbuster drug-indication pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, confirmed by clinical readout

FP

False Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, contradicted by clinical readout

FN

False Negative — predicted non-blockbuster drug-indication pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, contradicted by clinical readout

FIC

First-In-Class — novel mechanism of action and indication pair, no approved precedent

BIC

Best-In-Class — improved agent within an established class

DOR

Diagnostic Odds Ratio — measures discriminative power

MoA

Mechanism of Action — how a drug exerts its therapeutic effect

SoC

Standard of Care — current best available treatment

NCTID

ClinicalTrials.gov trial identifier (e.g., NCT12345678)

DATA PROVENANCE

- All predictions in this dossier are sourced from the BioinvestGPT validated prediction database.
- Each prediction is independently verifiable via its unique index number on data.bioinvestgpt.com.
- Clinical readout outcomes are sourced from official company press releases, ClinicalTrials.gov results, and peer-reviewed literature.
- This dossier was generated on April 8, 2026.

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Clinical trials are inherently uncertain. Regulatory approval, commercial success, and patient outcomes depend on numerous factors beyond the scope of this analysis, including but not limited to: regulatory authority decisions, manufacturing capabilities, competitive dynamics, payer coverage, and post-marketing safety signals.

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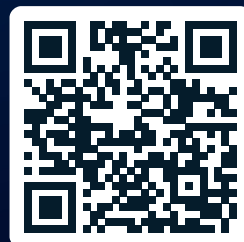
Evidence Dossier

Data-Free Head-to-Head Virtual Clinical Trials
with > 90% Ex-Ante Accuracy

April 8, 2026

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