Immunology

Effect-Size Predictions

Using Data-free Virtual Clinical Trials

96% accuracy across 144 Immunology trials

Overall: 96% across all 604 validated trials

BioinvestGPT

Evidence Dossier

April 8, 2026

Platform Credentials at a Glance

96%

Prospective Prediction Accuracy

Across 144 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	White-Box	Head-to-Head	144 of 604
Zero-Patient Input	Root Cause Explained	vs. Standard of Care	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

Immunology

144 of 604 validated trials

HAZARD RATIO GO/NO-GO THRESHOLD SPECTRUM

GO	**Strongly Superior**	HR < 0.3	*Transformative clinical benefit — megablockbuster potential*
GO	**Moderately Superior**	HR 0.3–0.6	*Commercially sufficient — blockbuster potential*
	HR = 0.6 THRESHOLD		
NO-GO	**Weakly Superior**	HR 0.6–0.8	*Marginal benefit — likely insufficient for market differentiation*
NO-GO	**Non-Superior**	HR 0.8–1.0	*No meaningful advantage over current standard of care*
NO-GO	**Inferior to SoC**	HR 1.0–1.2	*Patient harm risk — trial likely to fail primary endpoint*

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

SCALE

116 Drug Assets

77.1% First-in-Class ratio

COVERAGE

76 Sponsors

Public biopharma footprint

LEAD TIME

185 Days

Average advance prediction window

Full dataset: 96.0% (604 trials) | Filtered: 95.8% (144 trials) | Delta: -0.2pp

Predictive Performance Intelligence

Immunology

144 prospectively validated GO/NO-GO predictions

– –IMPAIRMENT NO-GO correct rate

Negative Predictive Value (NPV)

98%

86/88 NO-GO predictions validated

`TN / (TN + FN)`

98% 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%

138/144 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)

93%

52/56 GO predictions validated

`TP / (TP + FP)`

93% 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

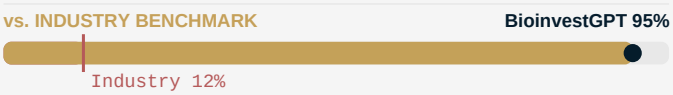
F1-Score

95%

Harmonic mean of Precision and Recall

`2×TP / (2×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

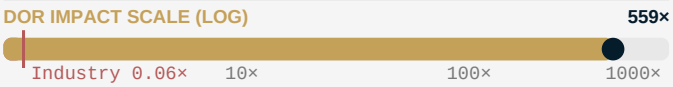
Diagnostic Odds Ratio (DOR)

559×

559× more likely correct than incorrect

`(TP × TN) / (FP × FN)`

BioinvestGPT GO/NO-GO predictions is **559 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

Immunology

Exhibit 1

Prediction accuracy remains consistently high across all therapeutic domains

BioinvestGPT's validation dataset spans 1 major therapeutic area, 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 1 domain. Accuracy = (TP + TN) / Total.

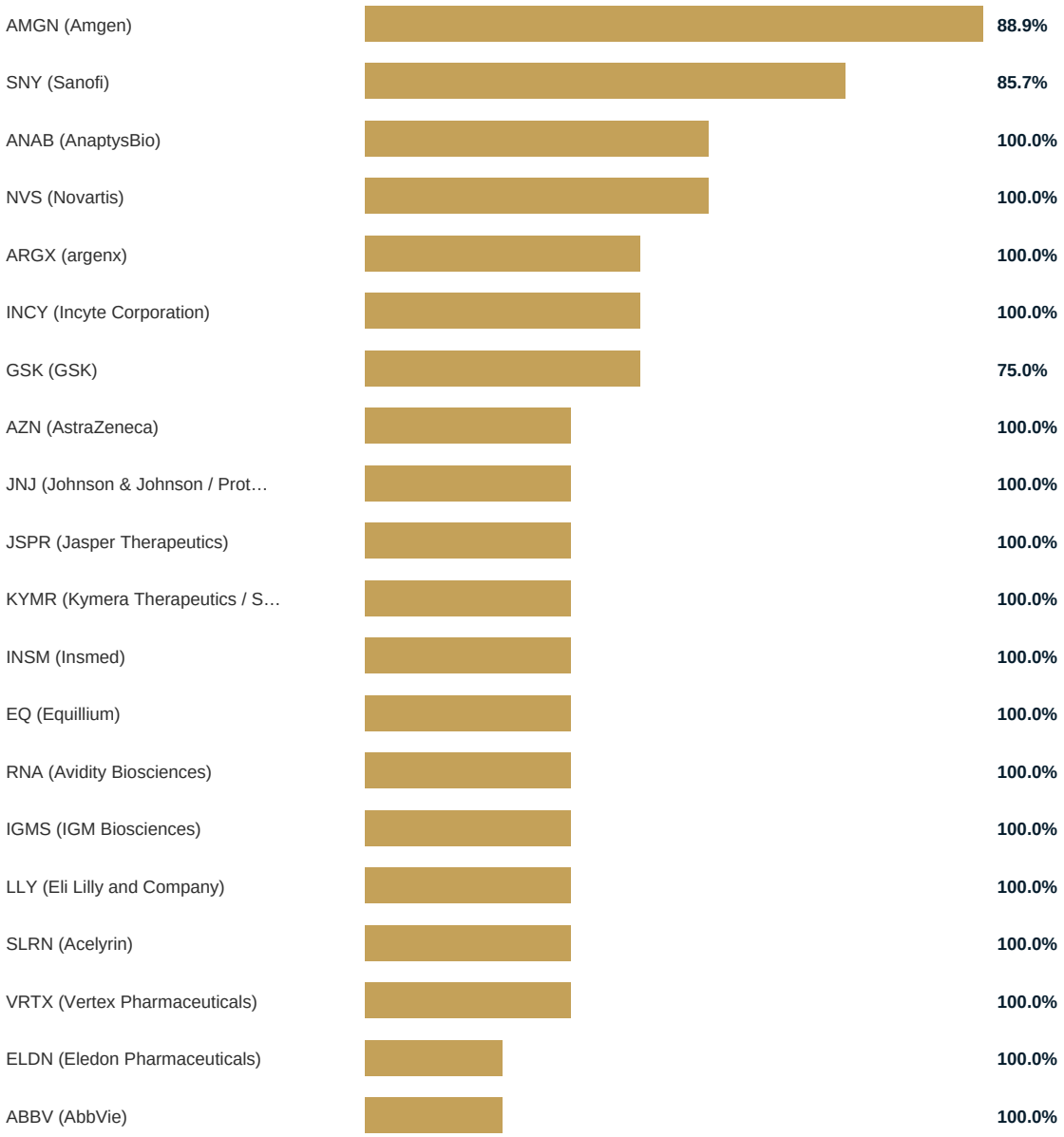
Sponsors Coverage Breakdown

Immunology

Exhibit 2

Validation spans 76 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: 76 | Average accuracy across top sponsors: 97.5%

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

Immunology

Exhibit 3

Validated across 116 distinct drug assets spanning 13 modalities

DRUG CLASSIFICATION

FIRST-IN-CLASS

111

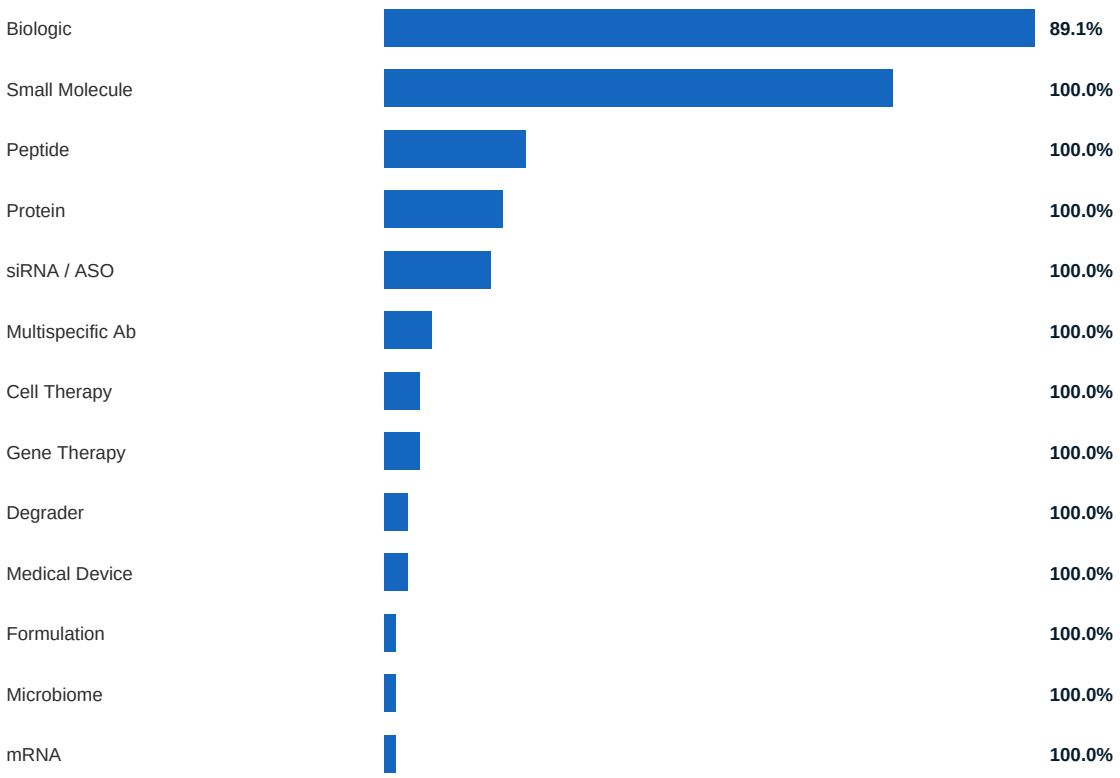
95.8% accuracy

BEST-IN-CLASS

33

95.8% accuracy

DRUG MODALITY DISTRIBUTION

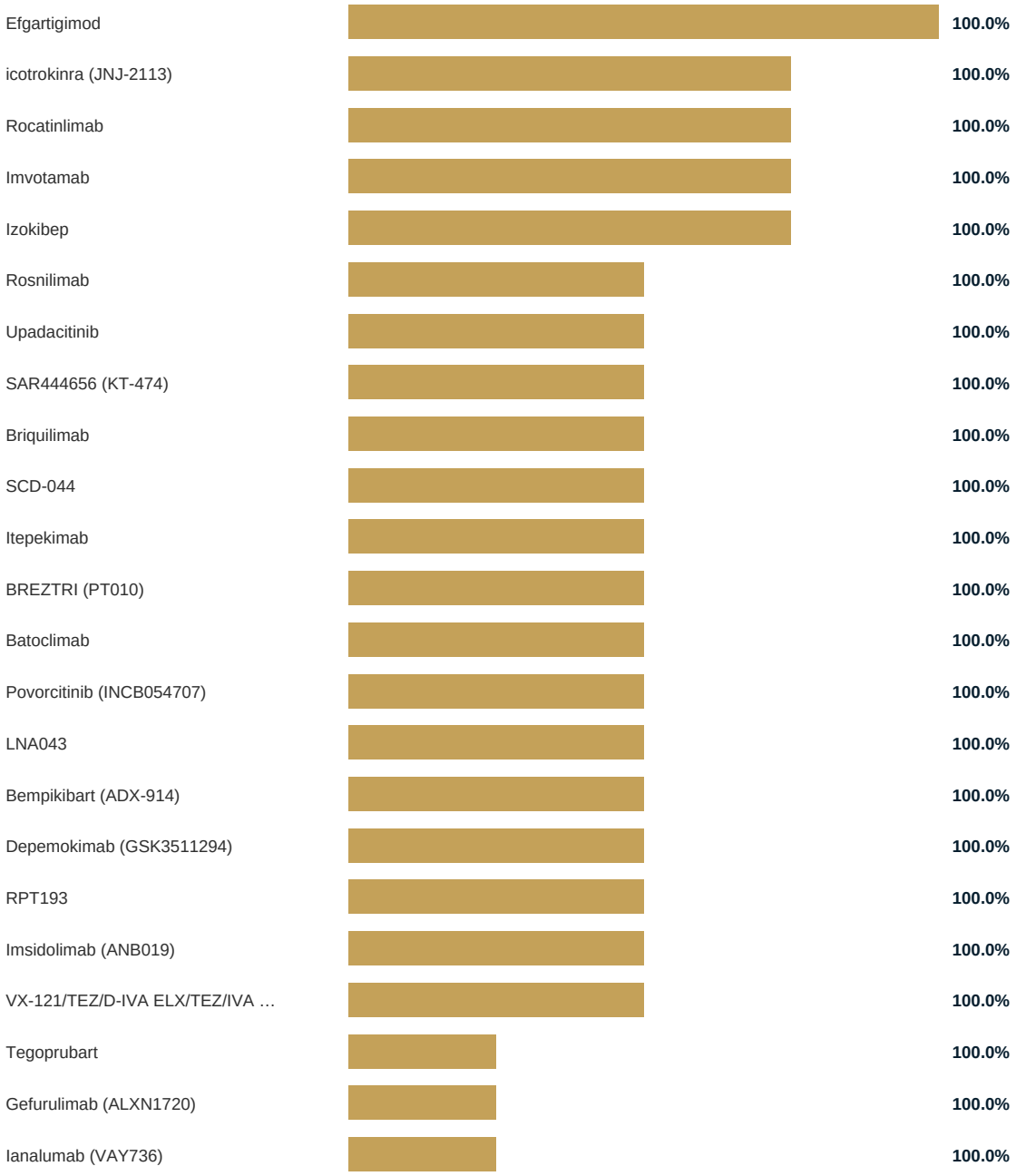


Drug Assets Coverage Breakdown

Immunology

Exhibit 4

Validated across 116 distinct drug assets with consistently high prediction accuracy



Total unique drug assets: 116 | 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.

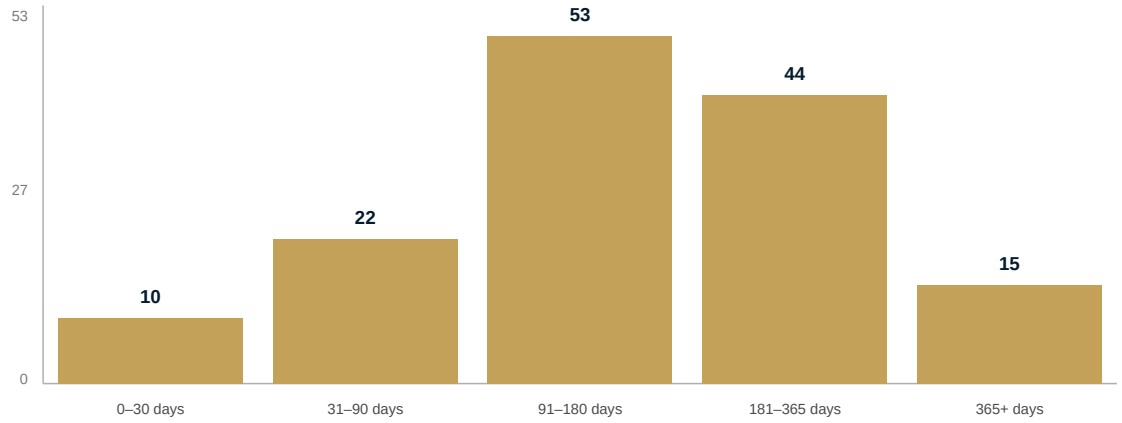
Temporal Integrity: Prospective Proof

Immunology

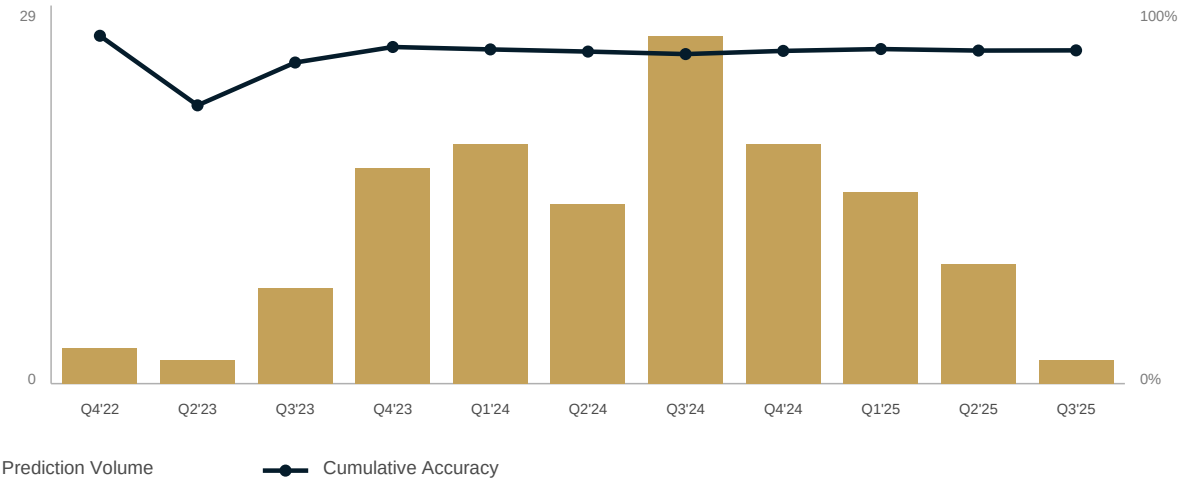
Exhibit 5

100% of predictions issued before clinical readout with median lead time of 185 days

LEAD TIME DISTRIBUTION



QUARTERLY PREDICTION VOLUME & CUMULATIVE ACCURACY



All 144 predictions were certified ex-ante, with an average lead time of 185 days before clinical readout. This temporal integrity is cryptographically verifiable and eliminates any possibility of post-hoc fitting.

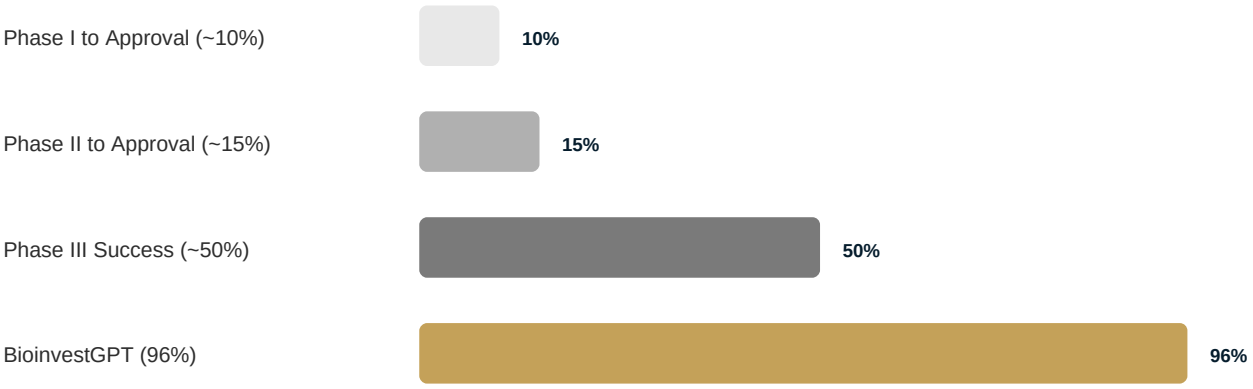
Competitive Benchmark Analysis

Immunology

Exhibit 6

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

CLINICAL DEVELOPMENT SUCCESS RATES



QUANTITATIVE BENCHMARK

Metric	BioinvestGPT	Industry Avg	Context
Accuracy	95.8%	~10-15%	Phase I-to-approval historical rate
Precision (PPV)	92.9%	~11%	Avg drug approval probability
NPV	97.7%	~60%	Combined Phase I–III attrition detection
F1-Score	94.5%	12%	Based on industry 10% nomination rate
DOR	559.0x	0.06x	Based on industry 10% nomination rate
Lead Time	185 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

$25.8B

86 of 88 NO-GO predictions validated × $300M avg trial cost

CAPTURED PORTFOLIO VALUE

$52.0B

52 of 56 GO predictions validated × $1B avg revenue

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
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 tulisokibart)	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)**
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)**
1971	**Gefurulimab (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: gefurulimab 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**	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	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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 276 **Sponsor: Novartis Pharmaceuticals (NVS)**	inferior to iscalimab that's further inferior to rituximab in ESSDAI as an adjunctive treatment to background therapies)		
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 2I (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)**
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 signifiant 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)**
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)**
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 Suppurativa** **Human Patients: 86** **Sponsor: Sanofi (SNY)**	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 yet non-superior to sonelokimab/bimekizumab/secukinumab)	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 (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)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: **True Negative (TN)**
1132	**Brepocitinib** **NCTID: NCT05437263** **Phase: Phase 3**	Date: 14 May 2025 Quarter: Q3'25 Batch 8 Technical: partial SUCCESS	Readout: 17 Sep 2025 **Lead Time: 126 days in advance** Interpretation: brepocitinib 30mg	Correct Prediction Conclusion: statistically significant and commercially sufficient

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	(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)	achieved 15.3 placebo-adjusted improvement in TIS at week 52 (p=0.0006)	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 Efzofitimod** **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: Efzofitimod 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); Efzofitimod + 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)**
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**	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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: United Therapeutics (UTHR)			
1207	**Barzolvolimab (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: barzolvolimab 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)**
625	**AT-1501 (Tegoprubart)** **NCTID: NCT05027906** **Phase: Phase 1 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: 48** **Sponsor: Eledon Pharmaceuticals (ELDN)**	Date: 26 Jan 2025 Quarter: Q2'25 Batch 6 Technical: partial SUCCESS (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)	Readout: 6 Aug 2025 **Lead Time: 192 days in advance** Interpretation: tegoprubart stablized 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 at 53 mL/min/1.73 m2 and achieved -2.98 iBox score at 12 months	Correct Prediction Conclusion: statistically maybe significant (iBox) and commercially maybe sufficient (weak efficacy in eGFR) Classification: **True Negative (TN)**
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)**
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**	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	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	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Moderate to Severe Atopic Dermatitis **Human Patients: 14** **Sponsor: Aclaris Therapeutics (ACRS)**	dupilumab and superior to upadacitinib)	score improvement at week 12-16 (see DOI-10.1016/j.ad.2024.10.067)	
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)**
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)**
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)**
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**	Date: 4 Nov 2024 Quarter: Q1'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo)	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 (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: E3ligase-binding IRAK4 degrader **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Atopic Dermatitis** **Human Patients: 70** **Sponsor: Kymera Therapeutics / Sanofi (KYMR / SNY)**	Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-superior to upadacitinib)		
1820	**Rezpegaldesleukin (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: rezpegaldesleukin 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)**
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)**
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)**
968	**Efgartigimod** **NCTID: NCT05523167** **Phase: Phase 2 Phase 3** **Class: First-In-Class**	Date: 11 Jul 2024 Quarter: Q3'24 Batch 16 Technical: FAILURE (statistically insignificant additive clinical benefit)	Readout: 11 Jun 2025 **Lead Time: 335 days in advance** Interpretation: efgartigimod achieved 14.8 placebo-adjusted improvement	Correct Prediction Conclusion: statistically significant yet weak clinical benefit and commercially insufficient

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: antibody fragment biologic **MoA: anti-FcRn antibody fragment** **Area: Immune System Diseases** **Indication: Active Idiopathic Inflammatory Myopathy** **Human Patients: 265** **Sponsor: argenx (ARGX)**	Commercial: FAILURE (commercially insufficient additive clinical benefit)	in mean TIS score (50.45 vs 35.65; P=0.0004); which is below the MCID threshold (>=20 point for TIS score)	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** **Sponsor: Insmed Incorporated (INSM)**	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)**
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-naive patients; superior to vosoritide's 4cm/year mean AGV for treatment-naive patients (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: **True Positive (TP)**
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**	Date: 18 Jul 2024 Quarter: Q3'24 Batch 18	Readout: 2 Jun 2025 **Lead Time: 319 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	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)	Interpretation: SCD044 failed to achieve statistically significant clinical benefit in EASI75 compared with placebo; further development discontinued	Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
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)**
1981	**Itepekimab** **NCTID: NCT04751487** **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: 1239** **Sponsor: Sanofi (SNY)**	Date: 15 May 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: 380 days in advance** Interpretation: Itepekimab (every four 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	Correct Prediction Conclusion: statistically insignificant and commercially insufficient (strongly inferior to mepolizumab) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
			link below)	
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)**
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 (KROS)**	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)**
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)**
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 probablysignificant and commercially probably insufficient Classification: **True Negative (TN)**
1797	**Soquelitinib** **NCTID: NCT06345404** **Phase: Phase 1** **Class: First-In-Class**	Date: 10 Nov 2024 Quarter: Q1'25 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in EASI75	Readout: 8 May 2025 **Lead Time: 179 days in advance** Interpretation: soquelitinib achieved 63% placebo-adjusted EASI75 at	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferior to upadacitinib)

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule **MoA: anti-ITK inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: atopic dermatitis** **Human Patients: 64** **Sponsor: Corvus Pharmaceuticals (CRVS)**	against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-inferior to upadacitinib)	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)	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)**
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)**
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**	Date: 18 Apr 2025 Quarter: Q3'25 Batch 1 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit in PASI75 compared with placebo)	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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Immune System Diseases **Indication: moderate to severe plaque psoriasis** **Human Patients: 221** **Sponsor: Sanofi (SNY)**	Commercial: FAILURE (commercially insufficient clinical benefit in PASI75/PASI90 moderately inferior to bimekizumab/ixekizumab and slightly inferior to icotrokinra)		
1757	**Amlitelimab** **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: amlitelimab 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)**
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 Diseas (aGVHD)** **Human Patients: 158** **Sponsor: Equillium (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)**
1814	**MRT-6160** **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)**	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4 Technical: SUCCESS (statistically signifiant 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)	Readout: 20 Mar 2025 **Lead Time: 137 days in advance** Interpretation: MRT6160 achieved >90% VAV1 degradation	Correct Prediction Conclusion: statistically significant (safety) and commercially TBD Classification: **True Positive (TP)**
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**	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	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Immunovant Sciences (IMVT)		batoclimab	
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)**
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 exon44 skip 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)**
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 supresses 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**	Date: 14 Jan 2025 Quarter: Q2'25 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in clinical	Readout: 10 Mar 2025 **Lead Time: 55 days in advance** Interpretation: icotrokinra achieved 20.1% placebo-adjusted clinical	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to PRA023)

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: peptide **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)**	response/remission compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in clinical response/remission)	remission rate at week 12 (p<0.001); 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)**
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 Tissue Diseases** **Indication: Moderate-to-sever Atopic Dermatitis** **Human Patients: 769** **Sponsor: Amgen (AMGN)**	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) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in vIGA-AD/ EASI75 (higher dose); superior to dupilumab yet inferior to upadacitinib)	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)**
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)**
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)**
1631	**iscalimab (CFZ533)** **NCTID: NCT0390552** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody**	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 Technical: FAILURE (statistically insignificant clinical benefit in ESSDAI or ESSPRI)	Readout: 31 Jan 2025 **Lead Time: 214 days in advance** Interpretation: iscalimab in cohort 1 failed to achieve statistical significance in dose-response	Correct Prediction Conclusion: statistically partially insignificant (cohort 1) and commercially insufficient (cohort 2)

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: anti-CD40 inhibitor **Area: Immune System Diseases** **Indication: Sjogren's Syndrome** **Human Patients: 273** **Sponsor: Novartis (NVS)**	Commercial: FAILURE (commercially insufficient clinical benefit in ESSDAI or ESSPRI inferior to efgartigimod that's further inferior to rituximab)	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	Classification: **True Negative (TN)**
1632	**LNA043** **NCTID: NCT04864392** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: ANGPLT3 agonist** **Area: Immune System Diseases** **Indication: Knee Osteoarthritis** **Human Patients: 583** **Sponsor: Novartis (NVS)**	Date: 1 Jul 2024 Quarter: Q3'24 Batch 14 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)	Readout: 31 Jan 2025 **Lead Time: 214 days in advance** Interpretation: LNA043 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)**
1633	**LNA043** **NCTID: NCT04814368** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: ANGPLT3 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)**
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 insignifiant 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)**
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** **Area: Immune System Diseases** **Indication: Severe Systemic Lupus Erythematosus** **Human Patients: 17**	Date: 26 Oct 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in BICLA/SRI4 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in BICLA/SRI4)	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 (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: IGM Biosciences (IGMS)			
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 an 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 ritlecitinib 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)**
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)**
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**	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	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%	Correct Prediction Conclusion: statistically significant yet weak (in FVCpp) and commercially insufficient (inferior to pirfenidone); Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Fibrosis **Human Patients: 240** **Sponsor: PureTech (PRTC)**	inferior to pirfenidone)	placebo-adjusted improvement in FVCpp	
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)**
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)**
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 Tissue Diseases** **Indication: Severe Alopecia Areata** **Human Patients: 40** **Sponsor: Q32 Bio (QTTB)**	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 score inferior to baricitinib)	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 patients)	Correct Prediction Conclusion: statistically probably significant and commercially probably insufficient Classification: **True Negative (TN)**
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)**
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**	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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Roivant Sciences (ROIV)			
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** **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)**	Date: 26 Apr 2024 Quarter: Q3'24 Batch 3 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 19 Nov 2024 **Lead Time: 207 days in advance** 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).	Correct Prediction Conclusion: statistically insignificant (in BICLA at week 24) and commercially 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)**
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-bexotegrast 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)**
1444	**tezepelumab**	Date: 5 Feb 2024	Readout: 8 Nov 2024	Correct Prediction

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT04851964 **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody** **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)**	Quarter: Q3'24 Batch 11 Technical: SUCCESS (statistically significant yet moderate additive clinical benefit) Commercial: SUCCESS (commercially sufficient yet moderate additive clinical benefit)	**Lead Time: 277 days in advance** Interpretation: tezepelumab achieved the efficacy primary endpoint of total endoscopic nasal polyp score at week 52 and mean nasal obstruction score by week 52	Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
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)**
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)**
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 bexotegrast)	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)**
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)**
1748	**Depemokimab (GSK3511294)** **NCTID: NCT05281523**	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7	Readout: 14 Oct 2024 **Lead Time: 62 days in advance**	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	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)	Interpretation: Depemokimab achieved the efficacy primary endpoint of total endoscopic nasal polyp score at week 52 and mean nasal obstruction score by week 52	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)**
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)**
1595	**WVE-N531** **NCTID: NCT04906460** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: siRNA** **MoA: stereopure exon 53 skpping antisense oligonucleotides** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 11** **Sponsor: Wave Life Sciences (WVE)**	Date: 12 May 2024 Quarter: Q3'24 Batch 6 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)	Readout: 24 Sep 2024 **Lead Time: 135 days in advance** Interpretation: a mean absolute dystrophin expression of 5.5%; which is relatively higher than competitor drugs.	Correct Prediction Note: Correct Technical prediction (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**	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6	Readout: 24 Sep 2024 **Lead Time: 45 days in advance**	Overall Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	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 amlitelimab; yet inferior to upadacitinib)	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).	and commercially maybe sufficient 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)**
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 bordline 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±/²-MAPK sma 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 benefitin 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** **Sponsor: Sanofi (SNY)**	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 biologic-naïve refractory CSU patients)	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 an barzolvolimab) Classification: **True Negative (TN)**
1749	**mepolizumab**	Date: 13 Aug 2024 Quarter: Q4'24 Batch 7	Readout: 6 Sep 2024 **Lead Time: 24 days in advance**	Missed Prediction

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	Technical: FAILURE (statistically insignificant additive clinical benefit in exacerbation ratio) Commercial: FAILURE (commercially insufficient additive clinical benefit in exacerbation ratio)	Interpretation: primary endpoint of annualized exacerbation reduction was met with statistically significant and clinically meaningful efficacy.	Note: due to suboptimal modelling of eosinophil count in the clinical setting of COPD. Conclusion: statistically significant and commercially sufficient Classification: **False Negative (FN)**
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)**
1188	**Izokibep** **NCTID: NCT05905783** **Phase: Phase 3** **Class: Best-In-Class** **Modality: small protein scaffold-based biologic** **MoA: IL-17A Inhibitior** **Area: Immune System Diseases** **Indication: Hidradenitis Suppurativa** **Human Patients: 258** **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)**
1183	**Izokibep** **NCTID: NCT05355805** **Phase: Phase 2** **Class: First-In-Class** **Modality: small protein scaffold-based biologic** **MoA: IL-17A Inhibitior** **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 achieved14% 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)**
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)**
1557	**PGN-EDO51** **NCTID: NCT06079736** **Phase: Phase 2** **Class: First-In-Class**	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in	Readout: 30 Jul 2024 **Lead Time: 98 days in advance** Interpretation: 5mg low-dose exon skipping level and dystrophin level	Correct Prediction Note: Correct Technical prediction (commercial data TBD)

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	dystrophin protein level) Commercial: FAILURE (commercially insufficient clinical benefit in the registrational endpoint 6MWD non-superior-to and non-inferior-to SRP-5051)	comparable to SRP5051 20mg (NCT04004065).	Conclusion: statistically significant and commercially TBD (pending functional efficacy data) Classification: **True Positive (TP)**
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)**
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)**
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)**
1440	**AV-101**	Date: 27 Jan 2024 Quarter: Q2'24 Batch 5	Readout: 17 Jun 2024 **Lead Time: 142 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	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)	Interpretation: no dose met the primary efficacy endpoint PVR and no dose achieved minimally clinical meaningful improvement in 6MWD (30 meters).	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)**
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)**
1260	**Povetacicept (ALPN-303)** **NCTID: NCT05732402** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: Fc fusion protein** **MoA: dual APRIL/BAFF antagonist** **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**	Date: 2 Oct 2023 Quarter: 2H'23 Batch 19 Technical: SUCCESS (statistically significant clinical benefit for proteinuria) Commercial: FAILURE (commercially insufficient clinical benefit due to low clinical efficacy on eGFR)	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 (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: ALPN Alpine Immune Sciences / Vertex Pharmaceuticals (ALPN (VRTX))			
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)**
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 ritlectinib 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)**
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)**
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**	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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	(ARCT)			
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)**
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)**
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)**
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** **Human Patients: 229** **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)**
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)**

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
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)**
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 Rhinosinusitis** **Human Patients: 196** **Sponsor: Lyra Therapeutics (LYRA)**	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)**
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)**
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 [Ravesloot 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**	Date: 6 Mar 2024 Quarter: Q2'24 Batch 11	Readout: 17 Apr 2024 **Lead Time: 42 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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 (BHVN)**	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)	Interpretation: unremarkable IGG data (-37%) inferior to the SoC efgatigimod IGG data (-75%).	Conclusion: statistically weak and commercially insufficient compared with efgartigimod Classification: **True Negative (TN)**
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)**
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)**
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)**
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; sueprior to the SoC octreitide 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)**
717	**Lebrikizumab (LY3650150)** **NCTID: NCT05372419** **Phase: Phase 3**	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS	Readout: 11 Mar 2024 **Lead Time: 471 days in advance** Interpretation: 68% EASI75 and 46%	Correct Prediction Conclusion: statistically significant and commercially sufficient

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	Commercial: SUCCESS	EASI90 55% itch reduction and 39% clear of skin; which is superior to 49% EASI75 achieved by dupilumab.	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 Inhibitior** **Area: Musculoskeletal Diseases** **Indication: Psoriatic Arthritis** **Human Patients: 351** **Sponsor: Acelyrin (SLRN)**	Date: 20 Nov 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially insufficient clinical benefit with non-superior-to-bimekizumab efficacy and inferior-to-bimekizumab toxicity)	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 infereior to 36% placebo-controlled ACR50 response at wk 16 and 0.4% discontinuation rate; achieved by bimekizumab (DOI-10.1016/S0140-6736(22)02303-0).	Correct Prediction Conclusion: statistically significant 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 (commerciall 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)**
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)**
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**	Date: 3 Dec 2023 Quarter: Q1'24 Batch 9 Technical: SUCCESS (statistically	Readout: 5 Feb 2024 **Lead Time: 64 days in advance** Interpretation: all primary and key	Correct Prediction Conclusion: statistically significant and commercially sufficient

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	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)**	significant clinical benefit non-inferior and non-superior to Trikafta) Commercial: SUCCESS (commercially sufficient clinical benefit with once-daily dosing regimen)	secondary endpoints of non-inferiority are met	(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** **Sponsor: Vertex Pharmaceuticals (VRTX)**	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)**
1089	**Lirentelimab (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)**
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)**
963	**Efgartigimod** **NCTID: NCT04598451** **Phase: Phase 3** **Class: First-In-Class** **Modality: antibody fragment**	Date: 4 Jul 2023 Quarter: 2H'23 Batch 9 Technical: FAILURE (statistically insignificant 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

Validated Trial Evidence: Filtered Registry (144 of 604 trials)

Filtered view: **Immunology**

#	Clinical Trial	Certified Prediction	Validation	Result
	biologic **MoA: anti-FcRn antibody fragment** **Area: Skin and Connective Tissue Diseases** **Indication: Pemphigus** **Human Patients: 222** **Sponsor: argenx (ARGX)**	Commercial: FAILURE (commercially insufficient additive clinical benefit)		Classification: **True Negative (TN)**

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 × TP / (2 × TP + FP + FN)`

DOR
`(TP × TN) / (FP × 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-indicatpion 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-indicatpion 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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