Rare Oncology

Effect-Size Predictions

Using Data-free Virtual Clinical Trials

96% accuracy across 105 Rare Oncology trials

Overall: 96% across all 604 validated trials

BioinvestGPT

Evidence Dossier

April 8, 2026

Platform Credentials at a Glance

96%

Prospective Prediction Accuracy

Across 105 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	105 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

Rare Oncology

105 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

100 Drug Assets

86.7% First-in-Class ratio

COVERAGE

77 Sponsors

Public biopharma footprint

LEAD TIME

220 Days

Average advance prediction window

Full dataset: 96.0% (604 trials) | Filtered: 96.2% (105 trials) | Delta: +0.2pp

Predictive Performance Intelligence

Rare Oncology

105 prospectively validated GO/NO-GO predictions

– –IMPAIRMENT NO-GO correct rate

Negative Predictive Value (NPV)

100%

69/69 NO-GO predictions validated

`TN / (TN + FN)`

100% 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%

101/105 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)

89%

32/36 GO predictions validated

`TP / (TP + FP)`

89% 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

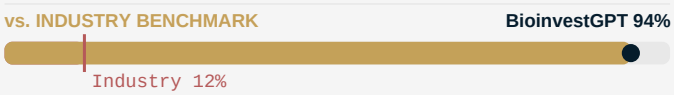
F1-Score

94%

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

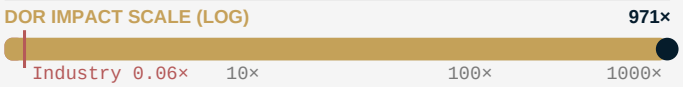
Diagnostic Odds Ratio (DOR)

971×

971× more likely correct than incorrect

`(TP × TN) / (FP × FN)`

BioinvestGPT GO/NO-GO predictions is **971 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

Rare Oncology

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.

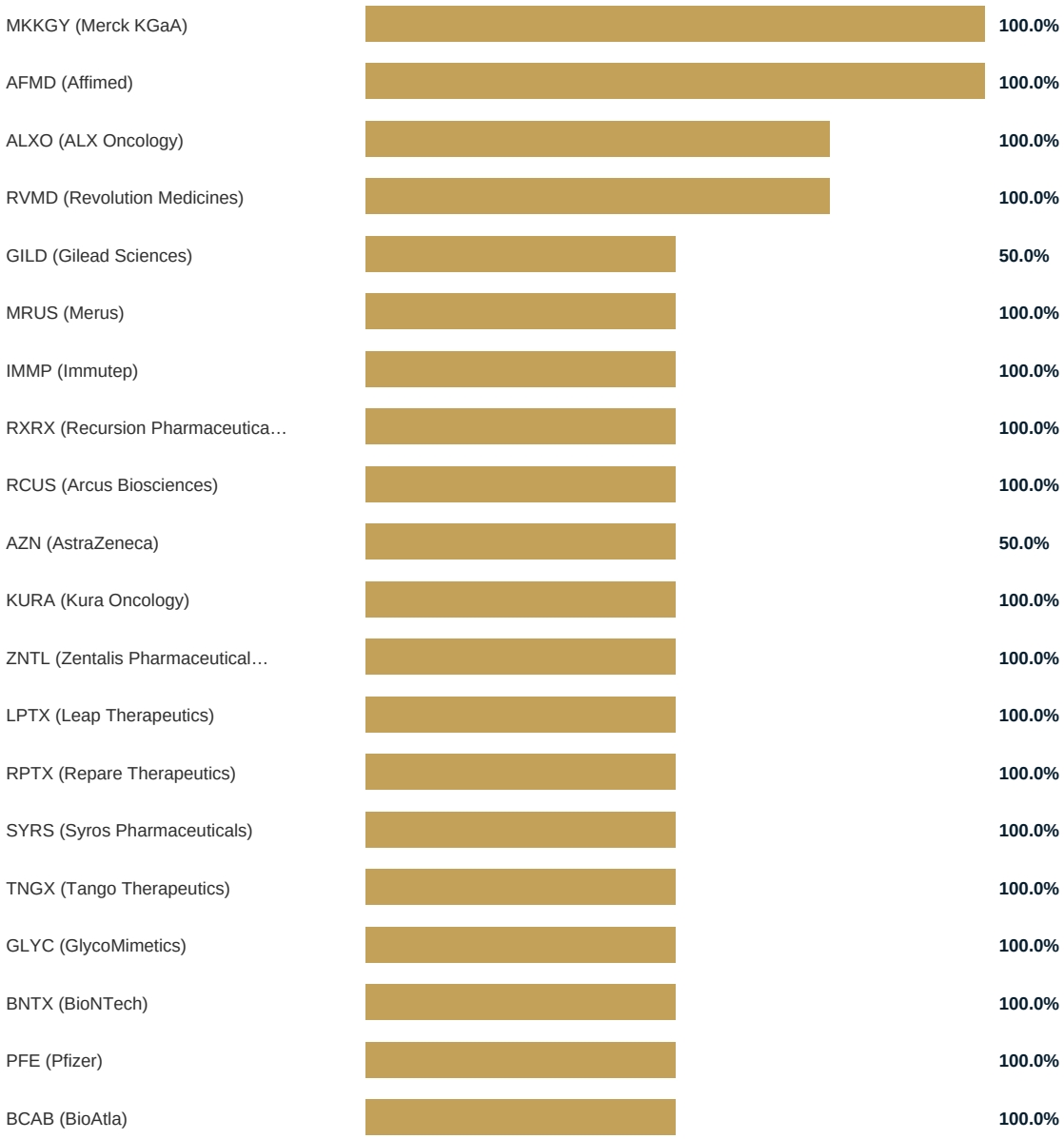
Sponsors Coverage Breakdown

Rare Oncology

Exhibit 2

Validation spans 77 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: 77 | Average accuracy across top sponsors: 95.0%

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

Rare Oncology

Exhibit 3

Validated across 100 distinct drug assets spanning 12 modalities

DRUG CLASSIFICATION

FIRST-IN-CLASS

91

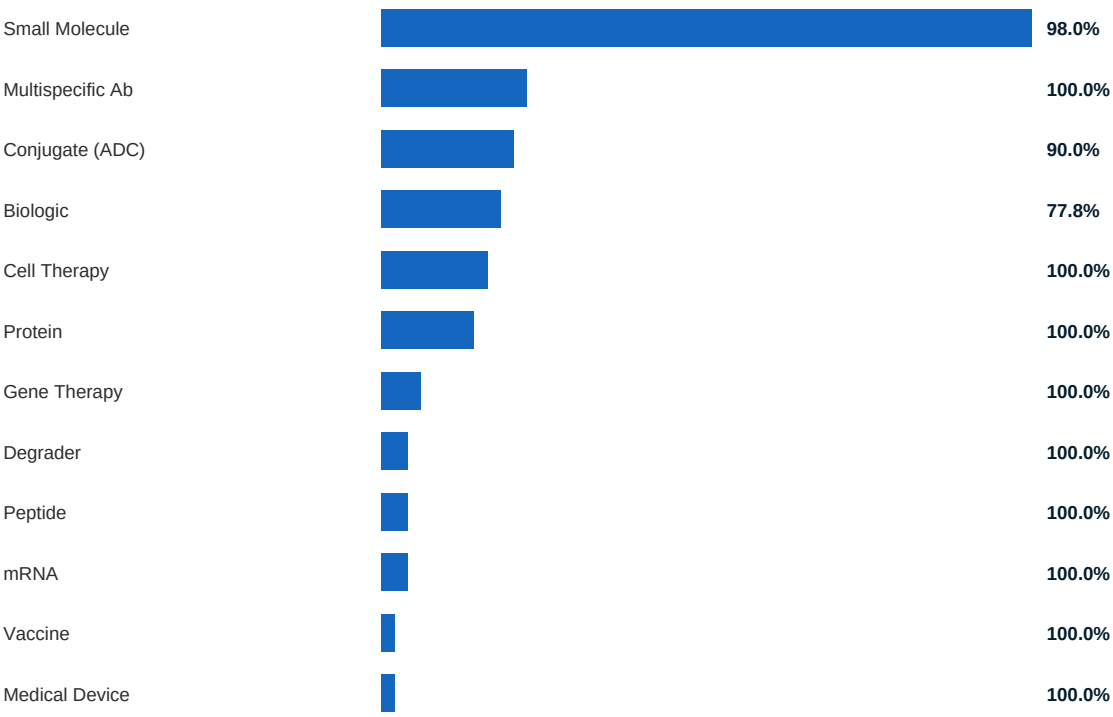
96.2% accuracy

BEST-IN-CLASS

14

96.2% accuracy

DRUG MODALITY DISTRIBUTION

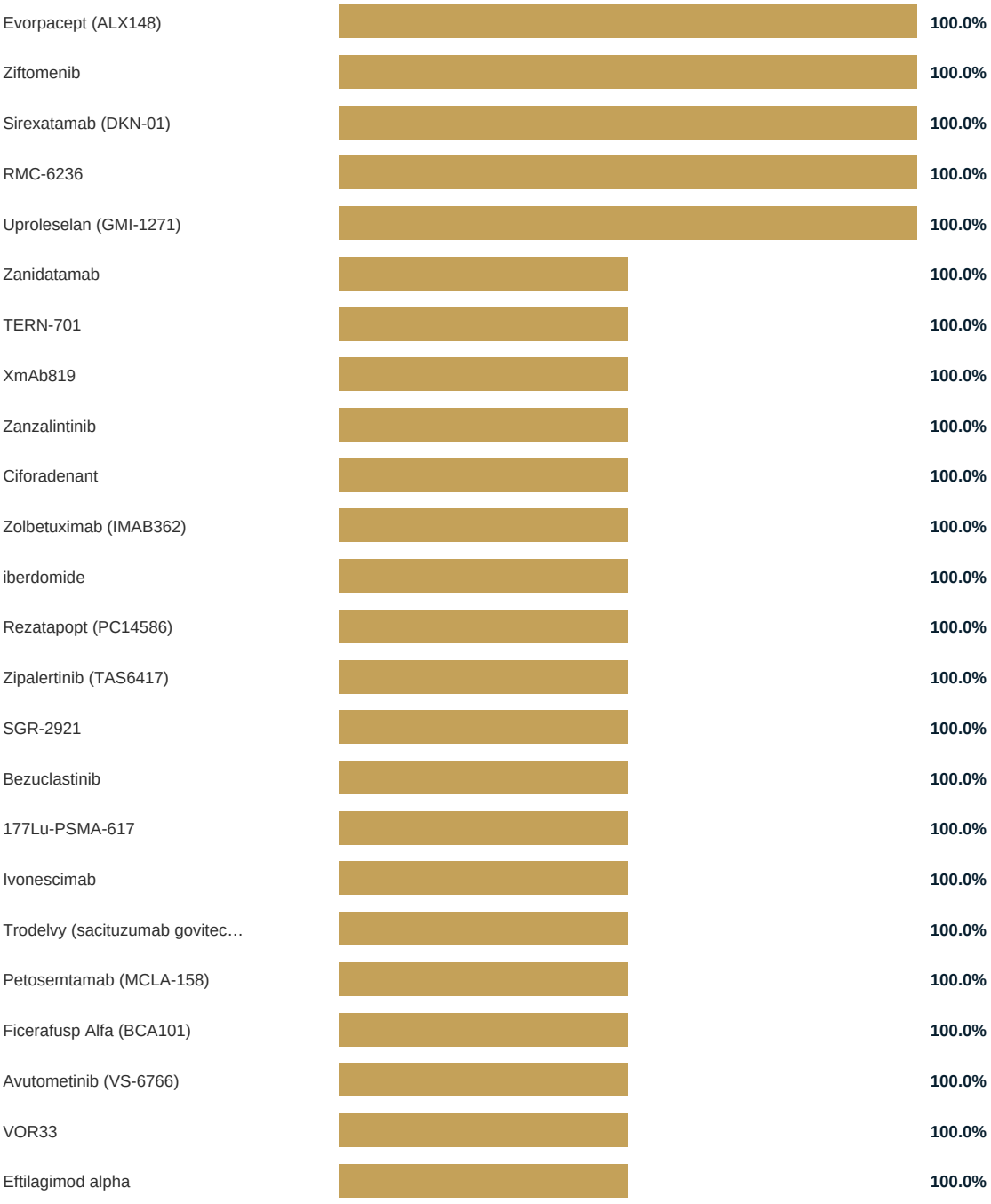


Drug Assets Coverage Breakdown

Rare Oncology

Exhibit 4

Validated across 100 distinct drug assets with consistently high prediction accuracy



Total unique drug assets: 100 | 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

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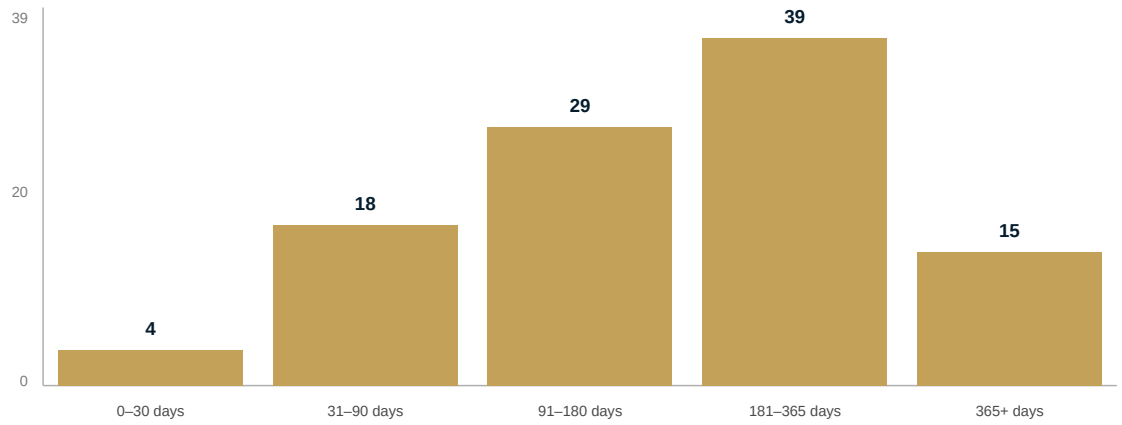
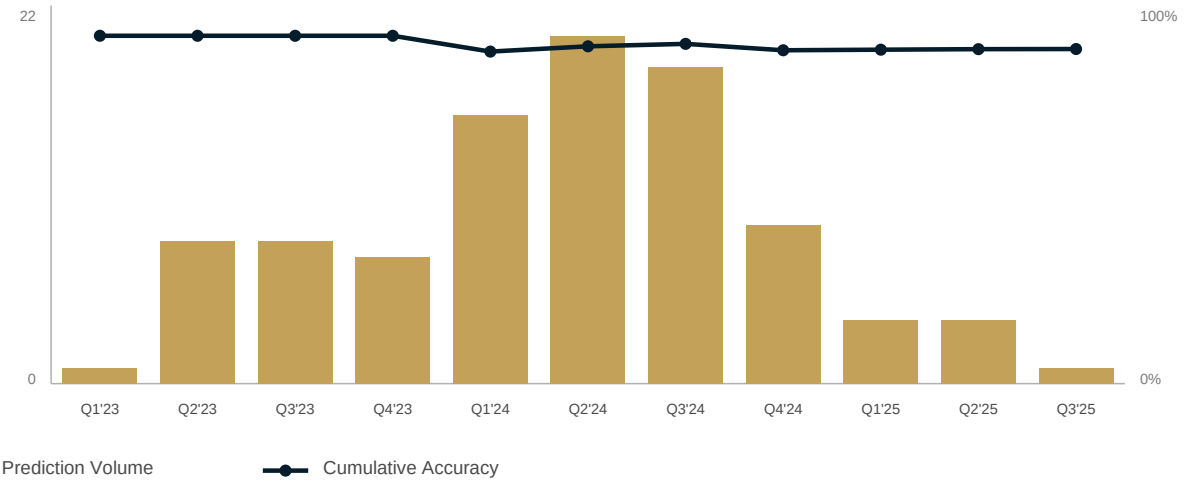
Exhibit 5

100% of predictions issued before clinical readout with median lead time of 220 days

LEAD TIME DISTRIBUTION



QUARTERLY PREDICTION VOLUME & CUMULATIVE ACCURACY



All 105 predictions were certified ex-ante, with an average lead time of 220 days before clinical readout. This temporal integrity is cryptographically verifiable and eliminates any possibility of post-hoc fitting.

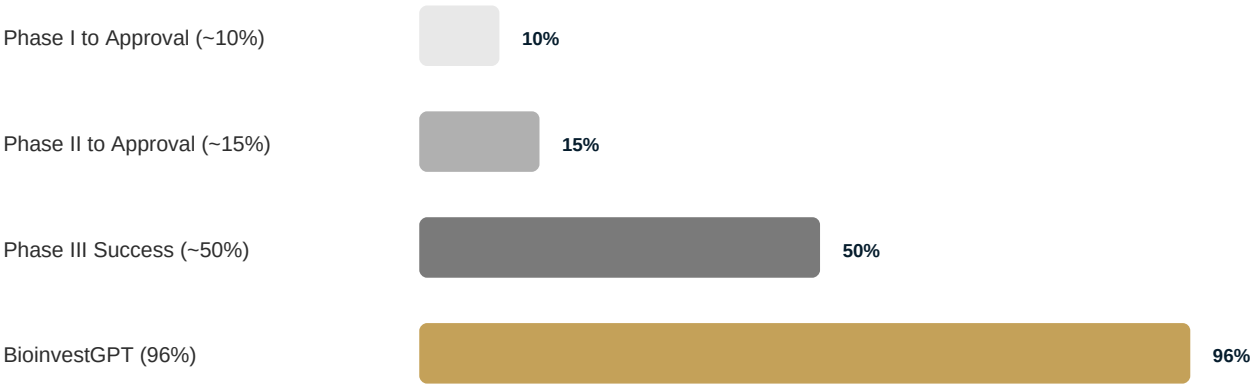
Competitive Benchmark Analysis

Rare Oncology

Exhibit 6

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

CLINICAL DEVELOPMENT SUCCESS RATES



QUANTITATIVE BENCHMARK

Metric	BioinvestGPT	Industry Avg	Context
Accuracy	96.2%	~10-15%	Phase I-to-approval historical rate
Precision (PPV)	88.9%	~11%	Avg drug approval probability
NPV	100.0%	~60%	Combined Phase I–III attrition detection
F1-Score	94.1%	12%	Based on industry 10% nomination rate
DOR	971.3x	0.06x	Based on industry 10% nomination rate
Lead Time	220 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

$20.7B

69 of 69 NO-GO predictions validated × $300M avg trial cost

CAPTURED PORTFOLIO VALUE

$32.0B

32 of 36 GO predictions validated × $1B avg revenue

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
590	**Zanidatamab** **NCTID: NCT05152147** **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: biparatopic anti-HER2 inhibitor** **Area: Neoplasms** **Indication: 1L HER2-positive Advanced or Metastatic Gastric and Esophageal Cancers** **Human Patients: 920** **Sponsor: Jazz Pharmaceuticals (JAZZ)**	Date: 19 Jan 2025 Quarter: Q2'25 Batch 3 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy]) Commercial: SUCCESS (commercially sufficient clinical benefit in OS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy])	Readout: 17 Nov 2025 **Lead Time: 302 days in advance** Interpretation: zanidatamab + tislelizumab + chemotherapy achieved superiority in both PFS and OS compared with the control arm trastuzumab plus chemotherapy; whereas zanidatamab + chemotherapy achieved superiority in PFS only (not in OS) compared with the control arm trastuzumab plus chemotherapy	Correct Prediction Conclusion: statistically significant (superior PFS for both doublet and triplet combo therapies) and commercially sufficient (superior OS for triplet combo therapy) Classification: **True Positive (TP)**
1853	**Bemarituzumab** **NCTID: NCT05111626** **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: FGFR2B inhibitor** **Area: Neoplasms** **Indication: 1L advanced gastric cancer/ GEJ cancer with FGFR2b over expression** **Human Patients: 515** **Sponsor: Amgen (AMGN)**	Date: 4 Dec 2024 Quarter: Q1'25 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to nivolumab + chemotherapy) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to nivolumab + chemotherapy)	Readout: 4 Nov 2025 **Lead Time: 335 days in advance** Interpretation: bemarituzumab + chemotherapy + nivolumab failed to deliver sufficient efficacy in PFS/ORR and further development has been discontinued	Missed Prediction Note: due to suboptimal modeling of drug MoA for ORR/PFS that has been permanently improved Conclusion: statistically insignificant (ORR/PFS) and commercially maybe sufficient (OS) Classification: **False Positive (FP)**
1697	**TERN-701** **NCTID: NCT06163430** **Phase: Phase 1** **Class: Best-In-Class** **Modality: small molecule** **MoA: BCR ABL1 myristoyl-pocket-binding TKI inhibitor** **Area: Neoplasms** **Indication: Relpased/refractory Chronic Myeloid Leukemia** **Human Patients: 100** **Sponsor: Terns Pharmaceuticals (TERN)**	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: SUCCESS (statistically significant clinical benefit in CR) Commercial: partial SUCCESS (commercially sufficient clinical benefit in CR non-superior non-inferior to ELVN001 for CML patients without T315I mutation) partial FAILURE (commercially insufficient clinical benefit in CR inferior to ELVN001 for CML patients with either T315I mutation or asciminib intolerance)	Readout: 3 Nov 2025 **Lead Time: 467 days in advance** Interpretation: TERN701 achieved 64% MMR at week 24	Correct Prediction Conclusion: statistically probably significant and commercially TBD Classification: **True Positive (TP)**
2017	**XmAb819** **NCTID: NCT05433142** **Phase: Phase 1** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: bispecific antibody that binds both ENPP3 and CD3** **Area: Neoplasms** **Indication: 2L+ advanced clear cell renal cell carcinoma (ccRCC)** **Human Patients: 95** **Sponsor: Xencor (XNCR)**	Date: 13 May 2025 Quarter: Q3'25 Batch 7 Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS compared with placebo with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS strongly inferior to cabozantinib)	Readout: 24 Oct 2025 **Lead Time: 164 days in advance** Interpretation: XmAb819 achieved 20% cORR (4/20) with 1 Grade 4 TEAE (5%); which is non-superior to the SoC cabozantinib that achieved 21% cORR (see add'l link below)	Correct Prediction Conclusion: statistically probably insignificant (non-superior ORR) and commercially TBD Classification: **True Negative (TN)**
2011	**Zanzalintinib** **NCTID: NCT05425940** **Phase: Phase 3** **Class: Best-In-Class** **Modality: small molecule** **MoA: multi-receptor TKI** **Area: Neoplasms** **Indication: 2L MSI-high Metastatic Colorectal Cancer** **Human Patients: 901**	Date: 7 May 2025 Quarter: Q3'25 Batch 6 Technical: partial FAILURE (statistically maybe significant yet very weak clinical benefit for XL092 + atezolizumab in ORR/PFS at most numerically superior to regorafenib) Commercial: FAILURE (commercially insufficient clinical benefit for XL092 + atezolizumab in OS non-superior to	Readout: 20 Oct 2025 **Lead Time: 166 days in advance** Interpretation: zanzalintinib + atezolizumab achieved statistically significant yet very weak OS in the ITT population (HR = 0.8 p=0.0045) yet statistically insignificant OS in the subset of patients without liver metastates (p = 0.087); compared with the regorafenib mono therapy	Correct Prediction Conclusion: partially statistically significant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Exelixis (EXEL)	regorafenib)		
1121	**Ciforadenant** **NCTID: NCT05501054** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: adenosine A2a Receptor Antagonist** **Area: Neoplasms** **Indication: 1L metastatic renal cell cancer (RCC)** **Human Patients: 50** **Sponsor: Corvus Pharmaceuticals (CRVS)**	Date: 8 May 2025 Quarter: Q3'25 Batch 6 Technical: FAILURE (statistically insignificant additive clinical benefit to nivolumab + ipilimumab in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefitS to nivolumab + ipilimumab in OS)	Readout: 17 Oct 2025 **Lead Time: 162 days in advance** Interpretation: ciforadenant + ipilimumab + nivolumab achieved 46% ORR and 11 months mPFS; non-superior to ipilimumab + nivolumab that achieved 42% ORR and 11.6 months mPFS (see add'l link below); ciforadenant + ipilimumab + nivolumab achieved a numerical improvement of OS HR by 0.05 compared with ipilimumab + nivolumab (0.69 vs 0.74)	Correct Prediction Conclusion: statistically insignificant (non-superior ORR/PFS) and commercially insufficient (non-superior OS) Classification: **True Negative (TN)**
1849	**Zolbetuximab (IMAB362)** **NCTID: NCT03816163** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: anti-CLDN18.2 inhibitor** **Area: Neoplasms** **Indication: 1L metastatic pancreatic adenocarcinoma (PDAC)** **Human Patients: 393** **Sponsor: Astellas Pharma (ALPMY)**	Date: 3 Dec 2024 Quarter: Q1'25 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS due to dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC alone)	Readout: 14 Oct 2025 **Lead Time: 315 days in advance** Interpretation: zolbetuximab + gemcitabine plus nab-paclitaxel failed to achieve superiority in OS compared with zolbetuximab + gemcitabine plus nab-paclitaxel alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1936	**iberdomide** **NCTID: NCT04975997** **Phase: Phase 3** **Class: Best-In-Class** **Modality: molecular glue degrader** **MoA: cereblon E3 ligase modulator that degrades IKZF1 and IKZF3** **Area: Neoplasms** **Indication: Relapsed or Refractory Multiple Myeloma** **Human Patients: 864** **Sponsor: Bristol Myers Squibb (BMY)**	Date: 4 Apr 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in ORR/PFS moderately superior to bortezomib + daratumumab + dexamethasone (DVd) and non-superior-non-inferior to belantamab mafodotin + pomalidomide + dexamethasone(BPd)) Commercial: SUCCESS (commercially sufficient additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in OS moderately superior bortezomib + daratumumab + dexamethasone (DVd) and slightly superior to belantamab mafodotin + pomalidomide + dexamethasone(BPd))	Readout: 23 Sep 2025 **Lead Time: 172 days in advance** Interpretation: iberdomide in combination with daratumumab and dexamethasone (IberDd) achieved a statistically significant superiority in MRD negativity (a deeper assessment than ORR) compared with the central arm of daratumumab/ bortezomib/dexamethasone (DVd); wait for OS data	Correct Prediction Conclusion: statistically significant (MRD negativity/ORR) and commercially TBD Classification: **True Positive (TP)**
1929	**Rezatapopt (PC14586)** **NCTID: NCT04585750** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: p53 reactivator** **Area: Neoplasms** **Indication: advanced Solid Tumors Harboring a TP53 Y220C Mutation** **Human Patients: 300** **Sponsor: PMV Pharmaceuticals (PMVP)**	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit as monotherapy in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy in OS non-superior to SoC)	Readout: 10 Sep 2025 **Lead Time: 208 days in advance** Interpretation: Rezatapopt achieved 33% ORR; moderately superior to chemotherapy that achieved 10-20% ORR for advanced solid tumors (see add'l link below); wait for OS data	Correct Prediction Conclusion: statistically significant (superior ORR) and commercially TBD Classification: **True Positive (TP)**
2051	**Zipalertinib (TAS6417)**	Date: 31 Jul 2025 Quarter: Q4'25 Batch 6	Readout: 9 Sep 2025 **Lead Time: 40 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05967689 **Phase: Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: 3rd-gen pan-mutant wt-sparing EGFR TKI** **Area: Neoplasms** **Indication: ex20in-mt advanced or metastatic Non-Small Cell Lung Cancer (NSCLC)** **Human Patients: 224** **Sponsor: Taiho Oncology / Cullinan Therapeutics (CGEM)**	Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS compared with placebo at least numerically superior to osimertinib for cohort A/B/C/D) Commercial: SUCCESS (commercially sufficient clinical benefit in OS slightly-to-moderately superior to osimertinib for cohort A/B/C/D)	Interpretation: Zipalertinib achieved a 62.5% ORR for 1L ex20in-mt NSCLC; moderately superior to osimertinib that achieved 25% ORR (see add'l link below); Zipalertinib achieved 21.9% ORR for 2L ex20in-mt NSCLCs; moderately superior to osimertinib that achieved 5% ORR (see DOI-10.1016/j.jtocrr.2022.100459); wait for OS data	Conclusion: statistically significant (superior ORR/PFS) and commercially TBD Classification: **True Positive (TP)**
1721	**SGR-2921** **NCTID: NCT05961839** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: CDC7 inhibitor** **Area: Neoplasms** **Indication: Relapsed/ Acute Myeloid Leukemia or Myelodysplastic Syndrome** **Human Patients: 66** **Sponsor: Schrödinger (SDGR)**	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant (additive) clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS)	Readout: 14 Aug 2025 **Lead Time: 373 days in advance** Interpretation: SGR-2921's further development has been discontinued due to unfavourable clinical benefit/risk profile	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
780	**Bezuclastinib** **NCTID: NCT05186753** **Phase: Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: cKIT D816V-mutation inhibitor** **Area: Neoplasms** **Indication: Indolent or Smoldering Systemic Mastocytosis** **Human Patients: 237** **Sponsor: Cogent Biosciences (COGT)**	Date: 14 Jan 2025 Quarter: Q3'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in MS2D2 non-superior-to avapritinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit featuring superior-to-avapritinib efficacy in OS and superior-to-avapritinib toxicity)	Readout: 7 Jul 2025 **Lead Time: 174 days in advance** Interpretation: bezuclastinib achieved placebo-adjusted -8.9 point in TSS/MS2D2 at week 24 (-24.3 bezuclastinib vs -15.4 placebo; 58% improvement over placebo; p= 0.0002); numerically superior to avapritinib's placebo-adjusted -6.4 point in TSS/MS2D2 at week 24 (-15.6 avapritinib vs -9.2 placebo; 70% improvement over placebo; p < 0.003) (see add'l link below)	Correct Prediction Conclusion: statistically significant (TSS/MS2D2) and commercially TBD (wait for OS data) Classification: **True Positive (TP)**
1650	**177Lu-PSMA-617** **NCTID: NCT04720157** **Phase: Phase 3** **Class: First-In-Class** **Modality: radionuclide drug conjugate** **MoA: anti-PSMA radionuclide drug conjugates** **Area: Neoplasms** **Indication: 1L PSMA-positive metastatic hormone-sensitive prostate cancer (mHSPC)** **Human Patients: 1145** **Sponsor: Novartis Pharmaceuticals (NVS)**	Date: 2 Jul 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit in rPFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 2 Jun 2025 **Lead Time: 335 days in advance** Interpretation: pluvicto + SoC achieved statistically significant clinical benefit in PFS compared with SoC alone; yet failed to achieve statistically significant clinical benefit in OS compared with SoC alone	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: **True Negative (TN)**
1667	**Ivonescimab** **NCTID: NCT06396065** **Phase: Phase 3** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: anti-PD-1 and anti-VEGF** **Area: Neoplasms** **Indication: 2L advanced EGFR-mutant NSCLC** **Human Patients: 420** **Sponsor: Summit Therapeutics (SMMT)**	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS non-superior to carboplatin + pemetrexed combotherapy) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to carboplatin + pemetrexed	Readout: 30 May 2025 **Lead Time: 294 days in advance** Interpretation: ivonescimab + chemotherapy achieved statistically significant clinical benefit in PFS compared with the SoC chemotherapy (HR=0.52; p<0.0001); yet failed to achieve statistically significant clinical benefit in OS compared with the SoC chemotherapy (HR=0.79 p=0.057)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
		combotherapy)		
1672	**Trodelvy (sacituzumab govitecan-hziy)** **NCTID: NCT05382299** **Phase: Phase 3** **Class: First-In-Class** **Modality: ADC** **MoA: anti-TROP2 ADC with SN38 payload** **Area: Neoplasms** **Indication: 1L metastatic Triple-Negative Breast Cancer (TNBC)** **Human Patients: 540** **Sponsor: Gilead Sciences (GILD)**	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PFS/ORR maybe superior to chemotherapy) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to chemotherapy)	Readout: 23 May 2025 **Lead Time: 318 days in advance** Interpretation: trodelvy achieved statistically significant superior-to-chemotherapy clinical benefit in PFS (without disclosure of the specific data and p-value; indicating probably weak efficacy in PFS); OS data not mature yet no OS detriment was observed	Correct Prediction Conclusion: statistically probably weakly significant (PFS) and commercially TBD (pending OS data); Classification: **True Negative (TN)**
1462	**Petosemtamab (MCLA-158)** **NCTID: NCT03526835** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: anti-EGFR-LGR5 bispecific antibody** **Area: Neoplasms** **Indication: 1L R/M HNSCC** **Human Patients: 567** **Sponsor: Merus (MRUS)**	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Readout: 22 May 2025 **Lead Time: 463 days in advance** Interpretation: petosemtamab + pembrolizumab achieved 63% ORR; 9 months mPFS; and 79% 12-month OS; superior to pembrolizumab + chemotherapy's 36% ORR; 5.8 months mPFS; and 53% 12-month OS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially sufficient (superior OS) Classification: **True Positive (TP)**
1773	**Ficerafusp Alfa (BCA101)** **NCTID: NCT04429542** **Phase: Phase 1** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: bispecific antibody with anti-EGFR and anti-TGFbeta targets** **Area: Neoplasms** **Indication: EGFR-driven Advanced Solid Tumors** **Human Patients: 292** **Sponsor: Bicara Therapeutics (BCAX)**	Date: 26 Aug 2024 Quarter: - Batch - Technical: partial SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS numerically superior to cetuximab yet inferior to petosemtamab as monotherapy or in combination with pembrolizumab) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS inferior to chemotherapy/cetuximab/petosemtamab as monotherapy or in combination with pembrolizumab)	Readout: 22 May 2025 **Lead Time: 269 days in advance** Interpretation: ficerafusp alfa + pembrolizumab achieved 54% ORR; 7.4 months mPFS; and 61.5% 12-month OS (see DOI-10.1200/JCO.2025.43.16_suppl.601); inferior to petosemtamab + pembrolizumab's 63% ORR; 9 months mPFS; and 79% 12-month OS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially insufficient (inferior-to-petosemtamab OS) Classification: **True Negative (TN)**
1812	**Avutometinib (VS-6766)** **NCTID: NCT05669482** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: MEK inhibitor** **Area: Neoplasms** **Indication: 1L Pancreatic Ductal Adenocarcinoma (PDAC)** **Human Patients: 40** **Sponsor: Verastem (VSTM)**	Date: 26 Oct 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to SoC chemotherapy alone) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC chemotherapy alone)	Readout: 22 May 2025 **Lead Time: 208 days in advance** Interpretation: avutometinib + defactinib + gemcitabine plus nab-paclitaxel (GnP) achieved 83% ORR (10/12); superior to GnP's 63% ORR for 1L PDAC (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (PFS/OS data pending) Classification: **True Positive (TP)**
1316	**VOR33** **NCTID: NCT04849910** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: cell therapy** **MoA: allogeneic CRISPAR/CAS9 genome-edited anti-CD33 HSPC cell therapy VOR33 + anti-CD33 ADC mylotarg** **Area: Neoplasms** **Indication: CD33+ acute myeloid leukemia (AML) or myelodysplastic syndromes**	Date: 7 Nov 2023 Quarter: 2H'23 Batch 27 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 8 May 2025 **Lead Time: 548 days in advance** Interpretation: VOR33 + mylotarg's further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	(MDS) **Human Patients: 67** **Sponsor: Vor Biopharma (VOR)**			
1240	**Eftilagimod alpha** **NCTID: NCT04811027** **Phase: Phase 2** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: a Soluble LAG-3 Fusion Protein** **Area: Neoplasms** **Indication: Recurrent or Metastatic HNSCC** **Human Patients: 171** **Sponsor: Immutep (IMMP)**	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 5 May 2025 **Lead Time: 609 days in advance** Interpretation: efti + pembrolizumab achieved 17.6 months mOS; superior to 10.7 months mOS achieved by cetuximab + chemotherapy or 11.3 months mOS achieved by anti-PD1 therapy + chemotherapy	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1592	**REC-2282** **NCTID: NCT05130866** **Phase: Phase 2 Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: HDAC inhibitor** **Area: Neoplasms** **Indication: Progressive Neurofibromatosis Type 2 (NF2) Mutated Meningiomas** **Human Patients: 92** **Sponsor: Recursion Pharmaceuticals (RXRX)**	Date: 11 May 2024 Quarter: Q4'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-microsurgery/radiosurgery efficacy)	Readout: 5 May 2025 **Lead Time: 359 days in advance** Interpretation: REC2282 failed to achieve statistically significant improvement in efficacy whose further development has thus been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1818	**REC-4881** **NCTID: NCT05552755** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: oral non-ATP-competitive MEK1/MEK2 inhibitor** **Area: Neoplasms** **Indication: Familial Adenomatous Polyposis (FAP)** **Human Patients: 67** **Sponsor: Recursion Pharmaceuticals (RXRX)**	Date: 3 Nov 2024 Quarter: Q1'25 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in polyp burden at week 12 against placebo with a positive duration-response relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in in polyp burden at week 24 superior to celecoxib)	Readout: 4 May 2025 **Lead Time: 182 days in advance** Interpretation: REC4881 achieved a median 43% reduction in polyp burden at week 13; superior to celecoxib's 28% reduction in polyp burden at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically probably significant and commercially probably sufficient Classification: **True Positive (TP)**
1093	**Evorpacept (ALX148)** **NCTID: NCT04675294** **Phase: Phase 2** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: CD47 blocker** **Area: Neoplasms** **Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)** **Human Patients: 189** **Sponsor: ALX Oncology (ALXO)**	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS non-superior to pembrolizumab + chemotherapy)	Readout: 25 Apr 2025 **Lead Time: 304 days in advance** Interpretation: evorpacept + SoC failed to achieve statistically significant clinical beneift in ORR/PFS/OS compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1092	**Evorpacept (ALX148)** **NCTID: NCT04675333** **Phase: Phase 2** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: CD47 blocker** **Area: Neoplasms** **Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)**	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS	Readout: 25 Apr 2025 **Lead Time: 304 days in advance** Interpretation: evorpacept + SoC failed to achieve statistically significant clinical beneift in ORR/PFS/OS compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 172 **Sponsor: ALX Oncology (ALXO)**	non-superior to pembrolizumab + chemotherapy)		
1195	**Tovecimig (CTX009)** **NCTID: NCT05506943** **Phase: Phase 2 Phase 3** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: bispecific antibody that inhibits both DLL4 and VEGF-A** **Area: Neoplasms** **Indication: advanced billiard tract cancers** **Human Patients: 150** **Sponsor: Compass Therapeutics (CMPX)**	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to paclitaxel monotherapy regardless of DLL4 baseline expression) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit in OS superior to paclitaxel monotherapy for high-DLL4-baseline-expression patients) partial FAILURE (commercially insufficient additive clinical benefit in OS non-superior to paclitaxel monotherapy for low-DLL4-baseline-expression patients)	Readout: 1 Apr 2025 **Lead Time: 149 days in advance** Interpretation: tovecimig + paclitaxel achieved 17.1% ORR superior to 5.3% ORR for paclitaxel alone (p=0.031); PFS and OS data not mature yet	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (OS pending) Classification: **True Positive (TP)**
971	**Amivantamab** **NCTID: NCT04487080** **Phase: Phase 3** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: bispecific antibody anti-EGFR and anti-MET inhibitor** **Area: Neoplasms** **Indication: EGFR-mutant Non-Small Cell Lung Cancer (NSCLC)** **Human Patients: 1074** **Sponsor: Johnson & Johnson (JNJ)**	Date: 5 Apr 2023 Quarter: Q2'2023 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (non-superior)	Readout: 26 Mar 2025 **Lead Time: 721 days in advance** Interpretation: amivantamab + lazertinib achieve statistically significant clinical benefit in mOS (HR = 0.75 p <0.005) cor osimertinib; In contrast amivantamab + lazertinib has 12% grade >=3 SAE; inferior to 1% grade >=3 SAE for osimertinib; The overall clinical benefit of amivantamab + lazertinib is grade 1 negligible (according to ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 2A (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (negligible OS benefit) Classification: **True Negative (TN)**
1249	**MRT-2359** **NCTID: NCT05546268** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: molecular glue degrader** **MoA: anti-GSPT1 molecular glue degrader** **Area: Neoplasms** **Indication: MYC-driven advanced solid tumours** **Human Patients: 174** **Sponsor: Monte Rosa Therapeutics (GLUE)**	Date: 30 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically maybe significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Mar 2025 **Lead Time: 537 days in advance** Interpretation: MRT2359 achieved 8% ORR (1/13) for MYC-positive patients and 3% ORR (1/37) for all patients; further development in SCLC; NSCLC; NE tumors discontinued due to low efficacy except for AR-resistant CRPC	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1673	**HexaBody-CD38 (GEN3014)** **NCTID: NCT04824794** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-CD38 mAb with Fc-domain-specific E430G mutation** **Area: Neoplasms** **Indication: relapsed or refractory multiple myeloma (RRMM)** **Human Patients: 130** **Sponsor: Genmab / Johnson & Johnson (GMAB / JNJ)**	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit in PFS/ORR superior to daratumumab for RRMM) Commercial: SUCCESS (commercially sufficient clinical benefit in CR/OS superior to daratumumab for RRMM)	Readout: 10 Mar 2025 **Lead Time: 244 days in advance** Interpretation: GEN3014 achieved 55% ORR and 7% CR; superior to 52% ORR and 2% CR achieved by the daratumumab arm	Correct Prediction Conclusion: statistically significant (ORR) and commercially probably sufficient (CR) Classification: **True Positive (TP)**
1586	**Ompenaclid**	Date: 8 May 2024 Quarter: - Batch -	Readout: 7 Mar 2025 **Lead Time: 303 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05983367 **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: SLC6A8 inhibitor** **Area: Neoplasms** **Indication: 2L RAS-mutant Metastatic Colorectal Cancer (mCRC)** **Human Patients: 70** **Sponsor: Merck KGaA (MKKGY)**	Technical: FAILURE (statistically insignificant additive clinical benefit to bevacizumab + chemotherapy in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit to bevacizumab + chemotherapy in OS)	Interpretation: ompenaclid received negative topline data and discontinued further development	Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1015	**Rusfertide** **NCTID: NCT05210790** **Phase: Phase 3** **Class: First-In-Class** **Modality: peptide** **MoA: peptide mimetic of hepcidin** **Area: Neoplasms** **Indication: Polycythemia Vera (PV)** **Human Patients: 250** **Sponsor: Protagonist Therapeutics (PTGX)**	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in phlebotomy eligibility superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit in PROMIS Short Form score superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib)	Readout: 3 Mar 2025 **Lead Time: 128 days in advance** Interpretation: rusfertide as an add-on treatment has met both the primary endpoint with 44% placebo-adjusted improvement in clinical response rate ($p<0.0001$) and four key secondary endpoints (phlebotomy/hematocrit control/PROMIS Fatigue SF8a/MFSAF TSS-7)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
511	**casdatifan (AB521)** **NCTID: NCT05536141** **Phase: Phase 1** **Class: Best-In-Class** **Modality: small molecule** **MoA: HIF2alpha inhibitor** **Area: Neoplasms** **Indication: 3L treatment for metastatic clear cell renal cell carcinoma (ccRCC)** **Human Patients: 302** **Sponsor: Arcus Biosciences (RCUS)**	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS compared with placebo) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS non-inferior to cabozantinib as a monotherapy and superior to cabozantinib as a combotherapy)	Readout: 15 Feb 2025 **Lead Time: 1 days in advance** Interpretation: casdatifan 100mg QD achieved 33% ORR and >6.8 months mPFS; superior to belzutifan that achieved 22% ORR and 5.6 months mPFS; as 3L treatment for ccRCC (10.1056/NEJMoa2313906) and non-inferior to cabozantinib that acheived 21% ORR and 7.4m mPFS as 3L treatment for ccRCC (see the add'l link below)	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: **True Positive (TP)**
1803	**CRB701** **NCTID: NCT06265727** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: ADC** **MoA: anti-nectin4** **Area: Neoplasms** **Indication: 2L treatment for nectin4-overexpressing advanced solid tumors** **Human Patients: 420** **Sponsor: Corbus Pharmaceuticals (CRBP)**	Date: 19 Oct 2024 Quarter: Q1'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS in 2L/3L clinical setting non-inferior-non-superior to enfortumab vedotin for nectin4-overexpressing advance solid tumors) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in OS non-inferior-non-superior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors that don't have FDA-approved drugs)	Readout: 14 Feb 2025 **Lead Time: 118 days in advance** Interpretation: CRB701 monotherapy achieved 44% ORR as 2L treatment for mUC patients previously treated with enfortumab vedotin (EV); comparable to EV monotherapy that achieve 37.5%-46.8% ORR as 2L treatment for mUC patients previously treated with chemo + anti-PD1 therapies (see add'l link below and DOI-10.1007/s00432-024-05717-2)	Correct Prediction Conclusion: statistically significant (in ORR non-superior non-inferior to EV) and commercially TBD (wait for OS data) Classification: **True Positive (TP)**
1861	**AZD0171** **NCTID: NCT04999969** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-LIF inhibitor** **Area: Neoplasms** **Indication: 1L treatment for advanced pancreatic ductal adenocarcinoma (PDAC)** **Human Patients: 126** **Sponsor: AstraZeneca (AZN)**	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS compared with chemotherapy alone) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to chemotherapy alone)	Readout: 6 Feb 2025 **Lead Time: 61 days in advance** Interpretation: AZD0171 + durvalumab + chemotherapy hasn't met the efficacy threshold and further development discontinued without disclosure of data	Missed Prediction Note: due to suboptimal drug MoA model that has been permanently corrected Conclusion: statistically insignificant and commercially insufficient Classification: **False Positive (FP)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
1087	**Ziftomenib** **NCTID: NCT05735184** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: MENIN-MLL1 inhibitor** **Area: Neoplasms** **Indication: R/R NPM1-m Acute Myeloid Leukemia** **Human Patients: 212** **Sponsor: Kura Oncology (KURA)**	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in CR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 5 Feb 2025 **Lead Time: 102 days in advance** Interpretation: ziftomenib achieved statistically significant CR/CRh without disclosing the actual CR/CRh data (which usually indicates unremarkable results); probably inferior to venetoclax + azacitidine's 24-38% CR/CRh (see the add'l link below) combotherapy TBD	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (as monotherapy) Classification: **True Negative (TN)**
1777	**Cemiplimab** **NCTID: NCT05208944** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: telomere-targeting agent THIO** **Area: Neoplasms** **Indication: 3L advanced NSCLC** **Human Patients: 182** **Sponsor: Maia Biotechnology (MAIA)**	Date: 2 Sep 2024 Quarter: Q4'24 Batch 15 Technical: partial SUCCESS (statistically significant moderate additive clinical benefit in ORR/PFS as 3L+ treatment) partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in ORR/PFS as 2L treatment) Commercial: partial SUCCESS (commercially sufficient yet moderate additive clinical benefit in OS in combination with cemiplimab superior to chemotherapy + cemiplimab as 3L+ treatment) partial FAILURE (commercially insufficient additive clinical benefit in OS in combination with cemiplimab non-superior to chemotherapy + cemiplimab as 2L treatment)	Readout: 4 Feb 2025 **Lead Time: 155 days in advance** Interpretation: THIO + cemiplimab achieved 16.9 months mOS (12.5 months mOS as the 95% CI lower bound); superior to the SoC chemotherapy that achieved 10.1 months mOS (see the add'l link below). wait for 2L data.	Correct Prediction Conclusion: statistically significant and commercially sufficient (3L) Classification: **True Positive (TP)**
1081	**ZN-c3 (azenosertib)** **NCTID: NCT05743036** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: Wee1 inhibitor** **Area: Neoplasms** **Indication: BRAF V600E mutant colorectal cancer** **Human Patients: 44** **Sponsor: Zentalis Pharmaceuticals (ZNTL)**	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	Readout: 29 Jan 2025 **Lead Time: 218 days in advance** Interpretation: azenosertib + encorafenib + cetuximab achieved 35-41% confirmed ORR as 1L treatment yet 0% confirmed ORR as 2L treatment. Hence; azenosertib + encorafenib + cetuximab hasn't met the efficacy threshold and further development discontinued	Correct Prediction Conclusion: statistically probably insignificant (combotherapy for patients not stratified by CCNE1 expression) yet weak additive efficacy and commercially insufficient (combotherapy discontinued) Classification: **True Negative (TN)**
526	**Sirexatamab (DKN-01)** **NCTID: NCT05480306** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-DKK1 inhibitor** **Area: Neoplasms** **Indication: 2L MSS Colorectal Cancer** **Human Patients: 189** **Sponsor: Leap Therapeutics (LPTX)**	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 **Lead Time: 275 days in advance** Interpretation: sirexatamab + bevacizumab + chemotherapy achieved a 12% delta in confirmed ORR (35% vs 23%); compared with bevacizumab + chemotherapy	Correct Prediction Conclusion: statistically maybe significant yet weak additive efficacy and commercially probably insufficient (weak additive ORR) Classification: **True Negative (TN)**
525	**Sirexatamab (DKN-01)** **NCTID: NCT04363801** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-DKK1 inhibitor** **Area: Neoplasms** **Indication: Gastric or Gastroesophageal Cancer** **Human Patients: 232**	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 **Lead Time: 275 days in advance** Interpretation: sirexatamab + tislelizumab + chemotherapy achieved a 3% delta in confirmed ORR (52% vs 49% in average) and -2.5 months delta in PFS (8.69 months in average vs 11.2 months in average) compared with tislelizumab + chemotherapy (though the median PFS for tislelizumab plus	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Leap Therapeutics (LPTX)		chemotherapy in the Phase 3 Rationale-305 study was 6.9 months (95% CI- 5.7; 7.2); further developments discontinued due to weak efficacy	
921	**Emiltatug Ledadotin (XMT-1660)** **NCTID: NCT05377996** **Phase: Phase 1** **Class: First-In-Class** **Modality: antibody-drug conjugate (ADC)** **MoA: DAR-6 anti-B7-H4 ADC with an AF-HPA payload** **Area: Neoplasms** **Indication: Triple Negative Breast Cancer Breast Cancer Endometrial Cancer Ovarian Cancer Fallopian Tube Cancer Primary Peritoneal Cavity Cancer Adenoid Cystic Carcinoma** **Human Patients: 319** **Sponsor: Mersana Therapeutics (MRSN)**	Date: 14 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with high toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 10 Jan 2025 **Lead Time: 271 days in advance** Interpretation: XMT1660 achieved 19% confirmed ORR for all B7-H4 high patients across all doses (11/57)	Correct Prediction Conclusion: statistically maybe significant yet weak clinical efficacy (low ORR) and commercially probably insufficient Classification: **True Negative (TN)**
428	**AFM24** **NCTID: NCT05109442** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: EGFR x CD16A tetravalent NK cell engager** **Area: Neoplasms** **Indication: Selected Advanced/Metastatic EGFR-expressing Cancers** **Human Patients: 148** **Sponsor: Affimed (AFMD)**	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 17 Dec 2024 **Lead Time: 292 days in advance** Interpretation: FM24 + atezolizumab achieved 18% confirmed ORR (6/33) for EGFRwt advanced NSCLC patients; numerically inferior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR (10.1016/j.lungcan.2018.12.015); AFM24 + atezolizumab achieved 24% confirmed ORR (4/17) for EGFRmut advanced NSCLC patients; inferior to osimertinib that achieved 71% ORR (10.1056/NEJMoa1612674)	Correct Prediction Conclusion: statistically significant yet weak (in ORR) and commercially insufficient Classification: **True Negative (TN)**
1770	**BBI-825** **NCTID: NCT06299761** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: RNR inhibitor** **Area: Neoplasms** **Indication: advanced solid tumours with resistance oncogene amplifications** **Human Patients: 42** **Sponsor: Boundless Bio (BOLD)**	Date: 29 Aug 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 12 Dec 2024 **Lead Time: 105 days in advance** Interpretation: BBI825's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: **True Negative (TN)**
851	**lunresertib (RP-6306) and camonsertib (RP-3500)** **NCTID: NCT04855656** **Phase: Phase 1** **Class: Best-In-Class** **Modality: small molecule** **MoA: PKMYT1 inhibitor and ATR inhibitor** **Area: Neoplasms** **Indication: Advanced Solid Tumors** **Human Patients: 364** **Sponsor: Repare Therapeutics (RPTX)**	Date: 18 Jan 2023 Quarter: 1H'23 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Dec 2024 **Lead Time: 694 days in advance** Interpretation: lunresertib + camonsertib achieved 18.5% confirmed ORR (5/27) for endometrial cancer; which is non-superior to pembrolizumab + lenvatinib that achieved 38% ORR (DOI-10.6004/jadpro.2022.13.1.4); lunresertib + camonsertib achieved 16.7% confirmed ORR (4/24) for platinum-resistant ovarian cancer; which is inferior to chemotherapy + bevacizumab that achieved 27.3% ORR	Correct Prediction Conclusion: statistically maybe significant yet weak (in ORR) and commercially insufficient (in ORR) Classification: **True Negative (TN)**
421	**CAN2409**	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4	Readout: 11 Dec 2024 **Lead Time: 127 days in advance**	Correct Prediction

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT01436968 **Phase: Phase 3** **Class: First-In-Class** **Modality: oncolytic viral gene therapy** **MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy** **Area: Neoplasms** **Indication: localized prostate cancer** **Human Patients: 711** **Sponsor: Candel Therapeutics (CADL)**	Technical: FAILURE (statistically insignificant additive clinical benefit in DFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Interpretation: CAN2409 + RT achieved statistically significant 14.5% relative improvement in DFS at month 54 (not the prespecified month 60) over RT alone (p=0.0155); CAN2409 + RT probably failed to achieve statistical significance in OS improvement (no mentioning of OS data in the topline readout)	Conclusion: statistically significant yet weak (borderline for DFS) and commercially insufficient (for OS) Classification: **True Negative (TN)**
1490	**AFM28** **NCTID: NCT05817058** **Phase: Phase 1** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: CD123 x CD16A tetravalent NK cell engager** **Area: Neoplasms** **Indication: Relapsed/ Acute Myeloid Leukemia** **Human Patients: 30** **Sponsor: Affimed (AFMD)**	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in ORR/CR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 Dec 2024 **Lead Time: 284 days in advance** Interpretation: AFM28 achieved 31% CR/CRi (5/16 for 250mg and 300mg); inferior to SoC that achieved 69% CR/CRi (see add'l link below)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: **True Negative (TN)**
1550	**R906289 Monosodium (R289 Na)** **NCTID: NCT05308264** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: IRAK1/IRAK4 inhibitor** **Area: Neoplasms** **Indication: R/R Lower-risk Myelodysplastic Syndromes (LR MDS) that have exhausted all the other treatment options** **Human Patients: 34** **Sponsor: Rigel Pharmaceuticals (RIGL)**	Date: 15 Apr 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 9 Dec 2024 **Lead Time: 238 days in advance** Interpretation: R289 achieved 40% hematologic responses (4 mg QD) and 30% RBC-TI mg QD) for 8 week and 1 Grade3 AST/Grade4 ALT TEAE	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: **True Positive (TP)**
1739	**Anitocabtagene-autoleucel** **NCTID: NCT05396885** **Phase: Phase 2** **Class: First-In-Class** **Modality: CAR-T therapy** **MoA: anti-BCMA D-Domain CAR-T cell therapy** **Area: Neoplasms** **Indication: Relapsed or Refractory Multiple Myeloma** **Human Patients: 110** **Sponsor: Arcellx (ACLX)**	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS non-superior to Carvykti) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in CR/OS non-superior to Carvykti)	Readout: 9 Dec 2024 **Lead Time: 121 days in advance** Interpretation: anito-cell achieved 97% ORR and 62% CR/sCR; non-superior to Carvykti that achieved 98% ORR and 67% sCR	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (non-superior to Carvykti) Classification: **True Negative (TN)**
1175	**RMC-6236** **NCTID: NCT05379985** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: tri-complex RAS(ON) multi-selective inhibitor** **Area: Neoplasms** **Indication: RAS Mutant Advanced Solid Tumors** **Human Patients: 614** **Sponsor: Revolution Medicines (RVMD)**	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: - Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 2 Dec 2024 **Lead Time: 505 days in advance** Interpretation: RMC6236 achieved 9% ORR (9% ORR is low and probably non-superior to KRAS(OFF) G12C inhibitors)	Correct Prediction Conclusion: statistically maybe significant and commercially probably insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
985	**NovoTTF-200T** **NCTID: NCT03377491** **Phase: Phase 3** **Class: First-In-Class** **Modality: medical device** **MoA: a device delivering low-intensity; wave-like; alternating electric fields to tumor sites** **Area: Neoplasms** **Indication: Pancreatic Cancer** **Human Patients: 571** **Sponsor: Novocure (NVCR)**	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 2 Dec 2024 **Lead Time: 103 days in advance** Interpretation: TTFields + SoC achieved 16.20 months mOS compared with 14.16 months in patients who received SoC alone (p=0.039); no PFS data announced in topline readout (usually indicating unremarkable PFS data)	Correct Prediction Conclusion: statistically significant (PFS data pending) and commercially sufficient (weakly superior OS) Classification: **True Positive (TP)**
1761	**Capivasertib** **NCTID: NCT04493853** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: pan-ATK small molecule inhibitor** **Area: Neoplasms** **Indication: Hormone-Sensitive Prostate Cancer** **Human Patients: 1012** **Sponsor: AstraZeneca (AZN)**	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in rPFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 26 Nov 2024 **Lead Time: 99 days in advance** Interpretation: capivasertib + SoC achieved superior rPFS compared with SoC alone; OS data not mature	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: **True Positive (TP)**
1484	**PYX-201** **NCTID: NCT05720117** **Phase: Phase 1** **Class: First-In-Class** **Modality: ADC** **MoA: anti-fibronectin-EDB ADC with cathepsin B-cleavage mediated release of auristatin payload** **Area: Neoplasms** **Indication: advanced solid tumor** **Human Patients: 80** **Sponsor: Pyxis Oncology (PYXS)**	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: FAILURE (statistically insignificant clinical benefit in PFS/OS/ORR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Nov 2024 **Lead Time: 225 days in advance** Interpretation: PYX201 achieved 26% ORR for advanced solid tumors; which is inferior to other targeted therapies for advanced solid tumors; e.g. 56% ORR of Enhertu for HER2+ advanced solid tumors (refer to additional press link for AstraZeneca's data)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient (weak efficacy) Classification: **True Negative (TN)**
1103	**OTX-2002** **NCTID: NCT05497453** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: mRNA medicine** **MoA: LNP-encapsulated mRNAs of ZF-DNMT and ZF-KRAB proteins** **Area: Neoplasms** **Indication: advanced solid tumor** **Human Patients: 190** **Sponsor: Omega Therapeutics (OMGA)**	Date: 27 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically significant yet weak clinical benefit for OTX2002 monotherapy and OTX2002 combotherapies) Commercial: FAILURE (commercially insufficient additive clinical benefit due to the inferior-to-atezolizumab+bevacizumab efficacy of OTX2002 combotherapies)	Readout: 14 Nov 2024 **Lead Time: 261 days in advance** Interpretation: OTX2002 achieved 50% DCR for HCC in line with historical benchmark range for approved TKIs and PD1 monotherapies (29-65%) and its further development is discontinued	Correct Prediction Conclusion: statistically probably significant and commercially insufficient (weak efficacy) Classification: **True Negative (TN)**
1371	**NXP800** **NCTID: NCT05226507** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: anti-HSF1 inhibitor** **Area: Neoplasms** **Indication: ADRI1a-mutated ovarian cancer** **Human Patients: 61** **Sponsor: Nuvectis Pharma (NVCT)**	Date: 8 Dec 2023 Quarter: Q1'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Nov 2024 **Lead Time: 342 days in advance** Interpretation: NXP800 achieved at most 9% ORR (1/11 unconfirmed); which is non-superior to the 8-13% ORR by nivolumab or PLD/GEM (Journal of Clinical Oncology DOI-10.1200/JCO.21.00334)	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
1779	**Letetresgene autoleucel (lete-cel; GSK3377794)** **NCTID: NCT03967223** **Phase: Phase 2** **Class: First-In-Class** **Modality: cell therapy** **MoA: anti-NY-ESO-1 TCR T-cell therapy** **Area: Neoplasms** **Indication: advanced synovial sarcoma (SS) or myxoid/round cell liposarcoma (MRCLS)** **Human Patients: 103** **Sponsor: Adaptimmune Therapeutics (ADAP)**	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet moderate additive clinical benefit in ORR/PFS as 1L treatment with moderate toxicity) SUCCESS (statistically significant additive clinical benefit in ORR/PFS as 2L treatment with moderate toxicity) Commercial: partial FAILURE (commercially insufficient additive clinical benefit in OS as 1L treatment) partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS as 2L treatment)	Readout: 13 Nov 2024 **Lead Time: 65 days in advance** Interpretation: lete-cel + SoC as 2L treatment achieved 42% ORR and 5.3 months PFS which is superior to the SoC alone (1L data not reported)	Correct Prediction Conclusion: statistically significant (2L) and commercially TBD (2L OS not mature) Classification: **True Positive (TP)**
1616	**Pimicotinib(ABSK021)** **NCTID: NCT05804045** **Phase: Phase 3** **Class: Best-In-Class** **Modality: small molecule** **MoA: anti-CSF1R inhibitor** **Area: Neoplasms** **Indication: tenosynovial giant cell tumor (TGCT)** **Human Patients: 90** **Sponsor: Merck KGaA (MKKGY)**	Date: 14 May 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to pexidartinib)	Readout: 12 Nov 2024 **Lead Time: 182 days in advance** Interpretation: pimicotinib achieved 50.8% placebo-adjusted ORR at week 25 (p<0.0001); which is superior to pexidartinib's 39% placebo-adjusted ORR at week 25 (P<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient; correct prediction Classification: **True Positive (TP)**
1624	**Tamibarotene** **NCTID: NCT04797780** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: RARalpha agonist** **Area: Neoplasms** **Indication: Myelodysplastic Syndrome with RARA gene overexpression** **Human Patients: 550** **Sponsor: Syros Pharmaceuticals (SYRS)**	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: FAILURE (statistically insignificant additive clinical benefit in in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	Readout: 12 Nov 2024 **Lead Time: 181 days in advance** Interpretation: Tamibarotene failed to achieve additional benefit in CR as the primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
943	**Revumenib (SNDX-5613)** **NCTID: NCT04065399** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: MENIN-MLL1 inhibitor** **Area: Neoplasms** **Indication: mNPM1-mutant relapsed/refractory Leukemias** **Human Patients: 413** **Sponsor: Syndax Pharmaceuticals (SNDX)**	Date: 18 Jun 2023 Quarter: 2H'23 Batch 6 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Nov 2024 **Lead Time: 513 days in advance** Interpretation: Revumenib achieved 23% CR/CRh; which is inferior to CLT019's 81% CR	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior efficacy compared with SoC) Classification: **True Negative (TN)**
1018	**TNG462** **NCTID: NCT05732831** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor** **Area: Neoplasms** **Indication: MTAP-deleted Solid Tumors** **Human Patients: 159** **Sponsor: Tango Therapeutics**	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: SUCCESS (commercially sufficient clinical benefit in OS)	Readout: 6 Nov 2024 **Lead Time: 101 days in advance** Interpretation: TNG462 achieved 43% ORR for relapsed/refractory cholangiocarcinoma; superior to 5% ORR achieved by second-line chemotherapy for advanced biliary tract cancer; including cholangiocarcinoma (Lancet DOI-10.1016/S1470-2045(21)00027-9)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	(TNGX)			
1019	**TNG908** **NCTID: NCT05275478** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor** **Area: Neoplasms** **Indication: MTAP-deleted Solid Tumors** **Human Patients: 192** **Sponsor: Tango Therapeutics (TNGX)**	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in OS)	Readout: 6 Nov 2024 **Lead Time: 101 days in advance** Interpretation: TNG908 exhibited overall weak efficacy (active for non-CNS solid tumors yet inactive for GBM)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: **True Negative (TN)**
1298	**SC291** **NCTID: NCT05878184** **Phase: Phase 1** **Class: Best-In-Class** **Modality: CAR-T therapy** **MoA: anti-CD19 CAR T cell therapy** **Area: Neoplasms** **Indication: r/r B-cell malignancies** **Human Patients: 16** **Sponsor: Sana Biotechnology (SANA)**	Date: 21 Oct 2024 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit due to inferior efficacy for NHL and non-superior efficacy for CLL compared with other anti-CD19 CAR T cell therapies)	Readout: 4 Nov 2024 **Lead Time: 14 days in advance** Interpretation: SC291 development discontinued without further disclosure of data	Correct Prediction Conclusion: statistically probably significant and commercially insufficient Classification: **True Negative (TN)**
1441	**Uproleselan (GMI-1271)** **NCTID: NCT03616470** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: selective E-selectin antagonist** **Area: Neoplasms** **Indication: Relapsed/ Acute Myeloid Leukemia** **Human Patients: 388** **Sponsor: GlycoMimetics (GLYC)**	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 29 Oct 2024 **Lead Time: 256 days in advance** Interpretation: uproleselan failed to achieve the EFS primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1765	**RMC-9805** **NCTID: NCT06040541** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: KRAS-G12D-ON inhibitor** **Area: Neoplasms** **Indication: KRAS G12D-Mutant Solid Tumors** **Human Patients: 444** **Sponsor: Revolution Medicines Inc. (RVMD)**	Date: 27 Aug 2024 Quarter: Q4'24 Batch 14 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS superior to tumor-specific SoC) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS non-superior to tumor-specific SoC)	Readout: 25 Oct 2024 **Lead Time: 59 days in advance** Interpretation: RMC9805 achieved 30% ORR; where is superior to the SoC chemotherapy's 9%-16% ORR (see add'l link below)	Correct Prediction Conclusion: statistically significant (superior in ORR) and commercially TBD (OS data not mature) Classification: **True Positive (TP)**
1700	**TYRA-300** **NCTID: NCT05544552** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: N540K-mutation-specific FGFR3 antagonist** **Area: Neoplasms** **Indication: Advanced Urothelial Carcinoma and Other Solid Tumors With FGFR3 Gene Alterations**	Date: 27 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS with superior-to-erdafitinib safety) Commercial: SUCCESS (commercially sufficient clinical benefit in OS/CR superior to erdafitinib)	Readout: 25 Oct 2024 **Lead Time: 90 days in advance** Interpretation: TYRA300 achieved 54.5% ORR and 10% SAE (Gr3 only no Gr4); superior to erdafitinib's 71% SAE (both Gr3 and Gr4) (Lancet DOI-10.1016/S1470-2045(21)00660-4)	Correct Prediction Conclusion: statistically significant (superior in safety) and commercially TBD (OS data not mature) Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 310 **Sponsor: Tyra Biosciences (TYRA)**			
1130	**naporafenib (ERAS254)** **NCTID: NCT05907304** **Phase: Phase 1** **Class: Best-In-Class** **Modality: small molecule** **MoA: RAF inhibitor** **Area: Neoplasms** **Indication: RAS-mutant advanced solid tumors** **Human Patients: 115** **Sponsor: Erasca (ERAS)**	Date: 25 Jun 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 24 Oct 2024 **Lead Time: 487 days in advance** Interpretation: naporafenib + trametinib achieved only 30% ORR; non-superior to trametinib monotherapy that achieved 33% ORR for advanced melanoma (10.1002/onco.13795)	Correct Prediction Conclusion: statistically insignificant (in ORR) and commercially TBD (OS data not mature) Classification: **True Negative (TN)**
1551	**Belzupacap Sarotalocan (AU-011)** **NCTID: NCT05483868** **Phase: Phase 1** **Class: First-In-Class** **Modality: conjugate** **MoA: HPV nanoparticles conjugated with infrared-activated IR700 as a photodynamic therapy** **Area: Neoplasms** **Indication: Bladder Cancer** **Human Patients: 21** **Sponsor: Aura Biosciences (AURA)**	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/CR) Commercial: FAILURE (commercialll insufficient clinical benefit for AU011 with inferior-to-pembrolizumab/tebentafusp-monotherapy efficacy in OS)	Readout: 17 Oct 2024 **Lead Time: 180 days in advance** Interpretation: Bel-sar achieved 50% CR (4/8); inferior to pembrolizumab's 100% CR at any time (ASCO 19 KEYNOTE-057)	Correct Prediction Conclusion: statistically significant and commercially insufficient (weak clinical benefit) Classification: **True Negative (TN)**
1734	**BTN211-01** **NCTID: NCT04503278** **Phase: Phase 1** **Class: First-In-Class** **Modality: CAR-T** **MoA: anti-CLDN6 CAR-T cell and CLDN6 mRNA vaccine** **Area: Neoplasms** **Indication: Advanced solid tumors** **Human Patients: 145** **Sponsor: BioNTech (BNTX)**	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS as monotherapy or in combination with CLDN6 mRNA vaccine) Commercial: FAILURE (commercially insufficient clinical benefit in OS as monotherapy or in combination with CLDN6 mRNA vaccine)	Readout: 17 Sep 2024 **Lead Time: 39 days in advance** Interpretation: BTN211-01 with/without CARVac achieved 5% real ORR (not counting tumor marker responses; there were 3/64 patients who achieved PR or CR) in testicular/ovarian cancer; very low efficacy.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically maybe significant (against placebo) and commercially TBD Classification: **True Negative (TN)**
1733	**BNT113** **NCTID: NCT04534205** **Phase: Phase 2** **Class: First-In-Class** **Modality: mRNA vaccine** **MoA: HPV16 E6/7 RNA-LPX mRNA vaccine** **Area: Neoplasms** **Indication: Head and Neck Cancer** **Human Patients: 285** **Sponsor: BioNTech (BNTX)**	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS against pembrolizumab) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to pembrolizumab + chemotherapy as 1L SoC)	Readout: 17 Sep 2024 **Lead Time: 39 days in advance** Interpretation: BNT113 + pembrolizumab achieved 40% uORR + 3.9-month mPFS; which is non-superior to 36% ORR + 4.9-month mPFS achieved be chemo + pembrolizumab in KEYNOTE-048 (Lancet DOI-10.1016/S0140-6736(19)32591-7t).	Correct Prediction Conclusion: statistically maybe significant (yet weak additive efficacy) and commercially TBD Classification: **True Negative (TN)**
1416	**ponsegromab** **NCTID: NCT05546476** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-GDF15 mAb inhibitor** **Area: Neoplasms** **Indication: Cancer Cachexia** **Human Patients: 187**	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Sep 2024 **Lead Time: 243 days in advance** Interpretation: ponsegromab exhibited non-positive dose-response relationship and failed to meet key secondary/exploratory endpoints (at most 4-point increase in FAACT-ACS; at most 2-point increase in FAACT-5IASS; CRCSD; physical activity; gait endpoints).	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Pfizer (PFE)			
1560	**TBio-4101 Pembrolizumab** **NCTID: NCT05576077** **Phase: Phase 1** **Class: First-In-Class** **Modality: cell therapy** **MoA: autologous TIL cell therapy** **Area: Neoplasms** **Indication: Advanced Solid Tumors** **Human Patients: 60** **Sponsor: Turnstone Biologics (TSBX)**	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 14 Aug 2024 **Lead Time: 113 days in advance** Interpretation: 25% ORR achieved by TBio-4101 + pembrolizumab for MSI-stable CRC vs 30%-40% ORR achieved by regorafenib+ novolumab (Fakih et al. Huyck 2023 eClinicalMedicine).	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: **True Negative (TN)**
1535	**LTX-315 Part 1 VP-315 Part 2** **NCTID: NCT05188729** **Phase: Phase 2** **Class: First-In-Class** **Modality: oncolytic peptide therapy** **MoA: oncolytic peptide immunotherapy derived from bovine lactoferrin** **Area: Neoplasms** **Indication: Basal Cell Carcinoma** **Human Patients: 80** **Sponsor: Verrica Pharmaceuticals (VRCA)**	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit in clinical clearance) Commercial: FAILURE (commercially insufficient clinical benefit inferior to imiquimod)	Readout: 14 Aug 2024 **Lead Time: 127 days in advance** Interpretation: 51% CR lower than 80% CR achieved by imiquimod (DOI- 10.1016/j.jaad.2003.11.066).	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to imiquimod) Classification: **True Negative (TN)**
1625	**Tamibarotene Venetoclax Azacitidine** **NCTID: NCT04905407** **Phase: Phase 2** **Class: First-In-Class** **Modality: synthetic retinoid** **MoA: RARalpha agonist** **Area: Neoplasms** **Indication: Acute Myeloid Leukemia** **Human Patients: 95** **Sponsor: Syros Pharmaceuticals (SYRS)**	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: FAILURE (statistically insignificant additive clinical benefit in in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	Readout: 12 Aug 2024 **Lead Time: 89 days in advance** Interpretation: CR/CRi achieved by tamibarotene + SoC vs 70% CR/CRi achieved by SoC; and trial terminated.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1554	**EO-3021** **NCTID: NCT05980416** **Phase: Phase 1** **Class: First-In-Class** **Modality: antibody-drug conjugate (ADC)** **MoA: DAR-2 anti-claudin18.2 ADC with MMAE as payload** **Area: Neoplasms** **Indication: Pancreas Neoplasm Stomach Neoplasm Gastrointestinal Neoplasms Digestive System Neoplasm Neoplasms by Site Neoplasms** **Human Patients: 120** **Sponsor: Elevation Oncology (ELEV)**	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit due to dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit with non-superior-to-zolbetuximab efficacy and non-superior-to-zolbetuximab toxicity)	Readout: 6 Aug 2024 **Lead Time: 105 days in advance** Interpretation: EO-3021 achieved 20% ORR which is significantly lower than 47% ORR achieved by EO-3021 in previous Chinese-only study; 42.8% ORR for CLDN18.2 > 20% and 0% ORR for Claudin 18.2 <20% Four dose-limiting toxicities at 2.9mg/kg dose.	Overall Correct Prediction Conclusion: statistically significant (moderate ORR) and commercially insufficient Classification: **True Negative (TN)**
456	**Pamrevlumab + Gemcitabine + Nab-paclitaxel or Pamrevlumab + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX**	Date: 15 May 2024 Quarter: Q3'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant additive clinical benefit in ORR/PFS) Commercial: FAILURE (commercially	Readout: 30 Jul 2024 **Lead Time: 76 days in advance** Interpretation: OS endpoint not met (p=0.55).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT03941093 **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-CTGF mAb inhibitor** **Area: Neoplasms** **Indication: Locally Advanced Pancreatic Cancer** **Human Patients: 284** **Sponsor: FibroGen (FGEN)**	insufficient additive clinical benefit in OS)		
1175	**RMC-6236** **NCTID: NCT05379985** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: pan-RAS-mutation ON inhibitor** **Area: Neoplasms** **Indication: RAS Mutant Advanced Solid Tumors** **Human Patients: 474** **Sponsor: Revolution Medicines (RVMD)**	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 15 Jul 2024 **Lead Time: 365 days in advance** Interpretation: 20-21% ORR at week 14 vs 16% ORR achieved by Nal-IRI + 5-FU/LV for any PDAC (see add link for Nal-IRI data in Lancet) or 21% ORR achieved by Sotorasib in CodeBreaK 100 trial NEJM.	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (weak ORR improvement) Classification: **True Negative (TN)**
1240	**Eftilagimod alpha** **Pembrolizumab** **NCTID: NCT04811027** **Phase: Phase 2** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: a Soluble LAG-3 Fusion Protein** **Area: Neoplasms** **Indication: Recurrent or Metastatic HNSCC** **Human Patients: 171** **Sponsor: Immutep (IMMP)**	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 12 Jul 2024 **Lead Time: 312 days in advance** Interpretation: 35.5% ORR vs 30.8% ORR for chemo+pembrolizumab in CPS <1 population (Burtness et al. 2022 J. Clin Oncol).	Correct Prediction Conclusion: statistically significant (superior to SoC ORR) and commercially TBD (OS data pending) Classification: **True Positive (TP)**
849	**RP-6306** **NCTID: NCT05147350** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: oral PKMYT1 inhibitor** **Area: Neoplasms** **Indication: Advanced Solid Tumors** **Human Patients: 36** **Sponsor: Repare Therapeutics (RPTX)**	Date: 15 Feb 2024 Quarter: Q2'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 26 Jun 2024 **Lead Time: 132 days in advance** Interpretation: 12% confirmed ORR (4/33) vs 30%-50% ORR for other X+ FOLDIRI combotherspies.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1585	**Xevinapant (Debio 1143)** **Cisplatin Intensity Modulation Radiation Therapy (IMRT)** **Placebo** **NCTID: NCT04459715** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: oral IAP inhibitor** **Area: Neoplasms** **Indication: Squamous Cell Carcinoma of the Head and Neck** **Human Patients: 730** **Sponsor: Merck KGaA (MKKGY)**	Date: 8 May 2024 Quarter: Q3'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 **Lead Time: 47 days in advance** Interpretation: unlikely to meet EFS primary endpoints and discontinued.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1610	**Xevinapant IMRT Placebo**	Date: 14 May 2024 Quarter: - Batch -	Readout: 24 Jun 2024 **Lead Time: 41 days in advance**	Overall Correct Prediction

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05386550 **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: oral IAP inhibitor** **Area: Neoplasms** **Indication: Head and Neck Cancer** **Human Patients: 166** **Sponsor: Merck KGaA (MKKGY)**	Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in DFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Interpretation: unlikely to meet DFS primary endpoints and discontinued.	Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
407	**Trilaciclib Placebo Gemcitabine Carboplatin** **NCTID: NCT04799249** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: CDK4/6 inhibitor** **Area: Neoplasms** **Indication: TNBC - Triple-Negative Breast Cancer** **Human Patients: 194** **Sponsor: G1 Therapeutics (GTHX)**	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit in OS) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 **Lead Time: 140 days in advance** Interpretation: OS endpoint not met	Missed Prediction Note: due to suboptimal combotherapy causal modeling in meastatic TNBC that has been permanently correcte… Conclusion: statistically insignificant and commercially insufficient Classification: **False Positive (FP)**
1079	**ZN-c3** **NCTID: NCT04814108** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: Wee1 inhibitor** **Area: Neoplasms** **Indication: Uterine Serous Carcinoma** **Human Patients: 76** **Sponsor: Zentalis Pharmaceuticals (ZNTL)**	Date: 25 May 2023 Quarter: Q2'23 Batch 21a Technical: FAILURE (statistically insignificant clinical efficacy in ORR in placebo-controlled trial and moderate clinical toxicity) Commercial: FAILURE (commercially insufficient clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 **Lead Time: 390 days in advance** Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
614	**SL-172154** **NCTID: NCT05275439** **Phase: Phase 1** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: CD47-CD40 fusion protein** **Area: Neoplasms** **Indication: Acute Myeloid Leukemia (AML) / Myelodysplastic Syndrome (MDS)** **Human Patients: 160** **Sponsor: Shattuck Labs (STTK)**	Date: 25 Jun 2023 Quarter: 2H'23 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 Jun 2024 **Lead Time: 355 days in advance** Interpretation: 67% ORR (MDS vs 73% ORR and 73% CR/mCR for azacitidine) and 43% ORR (AML; vs 69% ORR and 45% CR for a azacitidine + magrolimab as 1L for TP53 mutant AML).	Correct Prediction Conclusion: no additive efficacy compared with SoC 1L; thus commercially insufficient Classification: **True Negative (TN)**
1489	**AFM13 AB-101 Cyclophosphamide Fludarabine Interleukin-2** **NCTID: NCT05883449** **Phase: Phase 2** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: CD30 x CD16A tetravalent NK cell engager** **Area: Neoplasms** **Indication: Relapsed or Refractory Hodgkin Lymphoma Peripheral T Cell Lymphoma** **Human Patients: 154** **Sponsor: Affimed (AFMD)**	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Jun 2024 **Lead Time: 104 days in advance** Interpretation: 87.5% ORR (lower than 100% ORR for AFMD alone).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1546	**CNTY-101 IL-2 Lymphodepleting**	Date: 14 Apr 2024	Readout: 3 Jun 2024	Correct Prediction

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Chemotherapy **NCTID: NCT05336409** **Phase: Phase 1** **Class: First-In-Class** **Modality: CAR-NK cell therapy** **MoA: allogeneic anti-CD19 CAR-iNK cells with Allo-Evasion edits; IL-15 support; and EGFR safety switch** **Area: Neoplasms** **Indication: CD19-Positive B-Cell Malignancies** **Human Patients: 75** **Sponsor: Century Therapeutics (IPSC)**	Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to anti-CD19 CAR-T cell therapies)	**Lead Time: 50 days in advance** Interpretation: 40-60% ORR (vs 74.1% ORR Anti-CD19 CAR-T cell therapy HR001).	Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
910	**Tildacerfont** **NCTID: NCT05370521** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: CRF1R antagonist** **Area: Neoplasms** **Indication: Polycystic Ovary Syndrome** **Human Patients: 27** **Sponsor: Spruce Biosciences (SPRB)**	Date: 7 Aug 2023 Quarter: 2H'23 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 3 Jun 2024 **Lead Time: 301 days in advance** Interpretation: significant reduction in DHEAS -12.4% vs placebo +5.7% was observed (p = 0.020; vs -12% by metformin).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior) Classification: **True Negative (TN)**
1334	**Darovasertib** **NCTID: NCT05907954** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: potent selective oral PKC inhibitor** **Area: Neoplasms** **Indication: Localized Ocular Melanoma** **Human Patients: 82** **Sponsor: IDEAYA Biosciences (IDYA)**	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 **Lead Time: 77 days in advance** Interpretation: 75% confirmed eye saved.	Correct Prediction Conclusion: statistically significant and commercially sufficient (no neoadjuvant SoC established for ocular melanoma) Classification: **True Positive (TP)**
1094	**Evorpacept (ALX148)** **Enfortumab Vedotin** **NCTID: NCT05524545** **Phase: Phase 1** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: anti-CD47 blocker** **Area: Neoplasms** **Indication: Urothelial Carcinoma** **Human Patients: 30** **Sponsor: ALX Oncology (ALXO)**	Date: 22 Jul 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 2 Jun 2024 **Lead Time: 316 days in advance** Interpretation: 50% ORR (20 patients receiving treatments) vs. 64.5% ORR for pembrolizumab + enfortumab).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
1495	**Sacituzumab Govitecan-hziy** **Paclitaxel Docetaxel Vinflunine** **NCTID: NCT04527991** **Phase: Phase 3** **Class: First-In-Class** **Modality: ADC** **MoA: anti-TROP2 ADC with SN38 payload for lysosomal-degradation-mediated intracellular release** **Area: Neoplasms** **Indication: Metastatic or Locally Advanced Unresectable Urothelial Cancer** **Human Patients: 696**	Date: 5 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-chemotherapy efficacy in OS)	Readout: 30 May 2024 **Lead Time: 86 days in advance** Interpretation: OS primary endpoint not met.	Missed Prediction Note: due to suboptimal drug MoA modeling that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient (non-superior) Classification: **False Positive (FP)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Gilead Sciences (GILD)			
406	**Trilaciclib in Patients Receiving Sacituzumab Govitecan-hziy** **NCTID: NCT05113966** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: CDK4/6 inhibitor** **Area: Neoplasms** **Indication: Triple Negative Breast Cancer** **Human Patients: 30** **Sponsor: G1 Therapeutics (GTHX)**	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit for Trodelvy)	Readout: 28 May 2024 **Lead Time: 396 days in advance** Interpretation: 17.9 mOS vs 12.1 OS (trodelvy alone).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1303	**IK-930** **NCTID: NCT05228015** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: oral TEAD inhibitor** **Area: Neoplasms** **Indication: Advanced Solid Tumors** **Human Patients: 198** **Sponsor: Ikena Oncology (IKNA)**	Date: 31 Oct 2023 Quarter: 2H'23 Batch 25 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 28 May 2024 **Lead Time: 210 days in advance** Interpretation: 0% ORR.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1542	**CG0070 Pembrolizumab Injection n-dodecyl-B-D-maltoside** **NCTID: NCT04387461** **Phase: Phase 2** **Class: First-In-Class** **Modality: oncolytic virus therapy** **MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene** **Area: Neoplasms** **Indication: Non-Muscle Invasive Bladder Cancer** **Human Patients: 35** **Sponsor: CG Oncology (CGON)**	Date: 15 Apr 2023 Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit with superior-to-pembrolizumab-monotherapy efficacy in CR/PFS/OS)	Readout: 24 May 2024 **Lead Time: 405 days in advance** Interpretation: 54% CR (vs 42% CR for pembrolizumab alone).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1422	**Brentuximab Vedotin With Pembrolizumab** **NCTID: NCT04609566** **Phase: Phase 2** **Class: First-In-Class** **Modality: antibody-drug conjugate (ADC)** **MoA: anti-CD30 ADC with MMAE as payload** **Area: Neoplasms** **Indication: Melanoma Non-small Cell Lung Cancer Squamous Cell Carcinoma of the Head and Neck** **Human Patients: 140** **Sponsor: Pfizer (PFE)**	Date: 15 Jan 2024 Quarter: Q1'24 Batch 5 Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit to pembrolizumab more for melanoma than for NSCLC or HNSCC) Commercial: FAILURE (commercially insufficient additive clinical benefit with non-superior-to-SoC efficacy in ORR/PFS/OS)	Readout: 23 May 2024 **Lead Time: 129 days in advance** Interpretation: 13-21% ORR and 12.9-13.9 months OS and 17% TEAE discontinuation (vs 11.5-12 months OS for chemo alone or more for chemo+X).	Correct Prediction Conclusion: statistically significant and commercially non-superior to SoC (chemo alone) Classification: **True Negative (TN)**
1292	**AN0025 and Chemoradiotherapy** **NCTID: NCT05191667** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: PGE2 EP4 inhibitor**	Date: 19 Oct 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially	Readout: 23 May 2024 **Lead Time: 217 days in advance** Interpretation: 50% ORR (6/12) vs 63.5% ORR (1L tislelizumab + chemo; 68-88% ORR for CRT alone doi- 10.3390/cancers15010010).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms **Indication: Esophageal Cancer** **Human Patients: 32** **Sponsor: Adlai Nortye (ANL)**	insufficient additive clinical benefit)		
428	**AFM24 Atezolizumab 840 MG in 14 ML Injection** **NCTID: NCT05109442** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: EGFR x CD16A tetravalent NK cell engager** **Area: Neoplasms** **Indication: Selected Advanced/Metastatic EGFR-expressing Cancers** **Human Patients: 148** **Sponsor: Affimed (AFMD)**	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 23 May 2024 **Lead Time: 84 days in advance** Interpretation: 6.6% ORR and 5.9 month PFS vs 35-50% ORR and 4.7-6.4 month PFS for SoC (nintedanib plus docetaxel VARGADO study doi-10.1016/j.esmoop.2023.100879).	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to SoC) Classification: **True Negative (TN)**
1025	**BLU-222 Carboplatin Ribociclib Fulvestrant** **NCTID: NCT05252416** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: CDK2 inhibitor** **Area: Neoplasms** **Indication: Advanced Solid Tumors** **Human Patients: 366** **Sponsor: Blueprint Medicines (BPMC)**	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy or combotherapy)	Readout: 23 May 2024 **Lead Time: 391 days in advance** Interpretation: <5% ORR (unconfirmed) vs 22-23% ORR for SoC (16% ORR for chemo & 37-55% ORR enhertu).	Correct Prediction Conclusion: statistically significant and commercially inferior to SoC Classification: **True Negative (TN)**
1462	**MCLA-158 + Pembrolizumab** **NCTID: NCT03526835** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: anti-EGFR-LGR5 bispecific antibody** **Area: Neoplasms** **Indication: 1L HNSCC** **Human Patients: 567** **Sponsor: Merus (MRUS)**	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Readout: 23 May 2024 **Lead Time: 99 days in advance** Interpretation: 67% ORR for combo superior to 27.3% ORR for SoC.	Correct Prediction Conclusion: statistically significant and commercially TBD (pending OS data) Classification: **True Positive (TP)**
1239	**CAB-ROR2-ADC PD-1 inhibitor** **NCTID: NCT03504488** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: antibody-drug conjugate (ADC)** **MoA: anti-ROR2 ADC** **Area: Neoplasms** **Indication: TNBC or Head & Neck Cancer (Ph1) and NSCLC or Melanoma (Ph2)** **Human Patients: 420** **Sponsor: BioAtla (BCAB)**	Date: 30 Nov 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 May 2024 **Lead Time: 166 days in advance** Interpretation: 7% ORR for melanoma (vs 21-36% ORR by anti-PD1 + anti-CLTA4 / TIL cell therapy).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: **True Negative (TN)**
1235	**Ozuriftamab Vedotin (BA3021) PD-1 inhibitor** **NCTID: NCT05271604** **Phase: Phase 2** **Class: First-In-Class** **Modality: antibody-drug conjugate (ADC)** **MoA: anti-ROR2 ADC**	Date: 3 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 May 2024 **Lead Time: 254 days in advance** Interpretation: 15% ORR for SCCHN (vs 13-16% ORR by anti-PD1).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms **Indication: Head and Neck Cancer** **Human Patients: 80** **Sponsor: BioAtla (BCAB)**			
1441	**Uproleselan (GMI-1271)** **NCTID: NCT03616470** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: selective E-selectin antagonist** **Area: Neoplasms** **Indication: Relapsed/ Acute Myeloid Leukemia** **Human Patients: 388** **Sponsor: GlycoMimetics (GLYC)**	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 **Lead Time: 80 days in advance** Interpretation: OS primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
744	**Setanaxib Pembrolizumab** **NCTID: NCT05323656** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: NOX1/NOX4 dual inhibitor** **Area: Neoplasms** **Indication: Squamous Cell Carcinoma of Head and Neck (SCCHN)** **Human Patients: 55** **Sponsor: Calliditas Therapeutics (CALT)**	Date: 22 Dec 2023 Quarter: Q1'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 **Lead Time: 136 days in advance** Interpretation: base percentage change in tumor size primary endpoint not met yet PFS/OS secondary endpoints showed positive trends (not significant).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1543	**CG0070** **n-dodecyl-B-D-maltoside** **NCTID: NCT04452591** **Phase: Phase 3** **Class: First-In-Class** **Modality: oncolytic virus therapy** **MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene** **Area: Neoplasms** **Indication: Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin** **Human Patients: 190** **Sponsor: CG Oncology (CGON)**	Date: 15 Apr 2024 Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit with maybe inferior-to-pembrolizumab efficacy in CR/PFS)	Readout: 3 May 2024 **Lead Time: 18 days in advance** Interpretation: 75.2% CR any time at month 12 (vs 100% CR any time for pembrolizumab at month 12. ASCO 19 KEYNOTE-057); no grade 3 TEAE.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
1493	**ACR-368 Gemcitabine OncoSignature** **NCTID: NCT05548296** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: CHEK1/CHEK2 small molecule inhibitor with OncoSignature predictive biomarkers** **Area: Neoplasms** **Indication: Ovarian Carcinoma; Endometrial Adenocarcinoma; and Urothelial Carcinoma** **Human Patients: 390** **Sponsor: Acrivon Therapeutics (ACRV)**	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in the OncoSignature positive arm) Commercial: SUCCESS (commercially sufficient clinical benefit in the OncoSignature positive monotherapy arm with superior efficacy over the OncoSignature negative combotherapy arm)	Readout: 24 Apr 2024 **Lead Time: 52 days in advance** Interpretation: 50% ORR for oncosignature positive arm vs 0% Orr for oncosignature negative arm (p=0.0038) vs 42.3% ORR of mirvetuximab soravtansine for patients selected by FOLRalpha; anti-correlation between dosage and efficacy.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
1508	**ELVN-001** **NCTID: NCT05304377** **Phase: Phase 1 a/1b** **Class: Best-In-Class** **Modality: small molecule** **MoA: BCR-ABL1 and T315I selective tyrosine kinase inhibitor** **Area: Neoplasms** **Indication: Chronic Myeloid Leukemia** **Human Patients: 180** **Sponsor: Enliven Therapeutics (ELVN)**	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 11 Apr 2024 **Lead Time: 24 days in advance** Interpretation: 44% cumulative MRR even for previously treated with asciminib.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1307	**CT-0508 Pembrolizumab** **NCTID: NCT04660929** **Phase: Phase 1** **Class: First-In-Class** **Modality: CAR-Macrophage therapy** **MoA: anti-HER2 CAR-M1** **Area: Neoplasms** **Indication: HER2-positive Adenocarcinoma Bile Duct Cancer Biliary Tract Cancer Bladder Cancer Breast CancerBreast Neoplasm Carcinoma Ductal Carcinoma Hepatocellular Cancer Lung Cancer Non-Small Cell Carcinoma Ovarian Epithelial Carcinoma Small Cell Carcinoma Squamous Carcinoma Transitional Cell Colorectal Cancer Esophagogastric Junction Neoplasms Inflammatory Breast Cancer Stomach Neoplasms Malignant Neoplasms Ovarian Neoplasms Pancreatic Cancer HER2-positive Solid Tumors HER2-positive Breast Cancer HER2-positive Gastric Cancer HER-2 Protein Overexpression HER-2 Gene Amplification Prostate Cancer Head and Neck Cancer Endometrial Cancer Lung Cancer Small Cel** **Human Patients: 48** **Sponsor: Carisma Therapeutics (CARM)**	Date: 31 Oct 2023 Quarter: 2H'23 Batch 26 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 1 Apr 2024 **Lead Time: 153 days in advance** Interpretation: safe yet terminated due to insufficient efficacy.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1059	**Paltusotine** **NCTID: NCT05361668** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: SST2R agonist** **Area: Neoplasms** **Indication: Carcinoid Syndrome** **Human Patients: 36** **Sponsor: Crinetics Pharmaceuticals (CRNX)**	Date: 14 Aug 2023 Quarter: 2H'23 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to octreotide)	Readout: 12 Mar 2024 **Lead Time: 211 days in advance** Interpretation: 63% reduction flushing frequency and 60% reduction in bowel movement frequency p<0.0001; both superior to the 20-35% reduction in flushing and bowel movement achieved by SoC (DOI- 10.1093/annonc/mdy293.007).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1347	**Ziftomenib** **NCTID: NCT04067336** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: Menin-MLL1 inhibitor** **Area: Neoplasms** **Indication: Relapsed or**	Date: 28 Nov 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 30 Jan 2024 **Lead Time: 63 days in advance** Interpretation: 65% ORR with 70% Top CR; non-superior to chemo's 60%-70% CR.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (105 of 604 trials)

Filtered view: **Rare Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Refractory Acute Myeloid Leukemia **Human Patients: 199** **Sponsor: Kura Oncology (KURA)**			
508	**AB680 Zimberelimab** **Nab-paclitaxel Gemcitabine** **NCTID: NCT04104672** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: CD73 inhibitor** **Area: Neoplasms** **Indication: Advanced Pancreatic Cancer** **Human Patients: 195** **Sponsor: Arcus Biosciences (RCUS)**	Date: 18 Jun 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 16 Jan 2024 **Lead Time: 212 days in advance** Interpretation: ORR/OS/PFS endpoints not met for both Q+ SoC and QZ+ SoC with mOS trend (15 vs 12 months for SoC).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

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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