Infections, Eye/Skin/Muscul

Effect-Size Predictions

Using Data-free Virtual Clinical Trials

96% accuracy

across 80 Infections, Eye/Skin/Muscul trials

Overall: 96% across all 604 validated trials

BioinvestGPT

Evidence Dossier

April 8, 2026

Platform Credentials at a Glance

96%

Prospective Prediction Accuracy

Across 80 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	80 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

Infections, Eye/Skin/Muscul

80 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

73 Drug Assets

78.8% First-in-Class ratio

COVERAGE

55 Sponsors

Public biopharma footprint

LEAD TIME

185 Days

Average advance prediction window

Full dataset: 96.0% (604 trials) | Filtered: 96.3% (80 trials) | Delta: +0.2pp

Predictive Performance Intelligence

Infections, Eye/Skin/Muscul

80 prospectively validated GO/NO-GO predictions

– –IMPAIRMENT NO-GO correct rate

Negative Predictive Value (NPV)

100%

48/48 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%

77/80 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)

91%

29/32 GO predictions validated

`TP / (TP + FP)`

91% of BioinvestGPT GO predictions are prospectively independently validated as commercially sufficient drugs. A GO signal identifies **blockbuster FIC/BIC assets** with high reliability, enabling **revenue-maximizing** portfolio predictions.

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

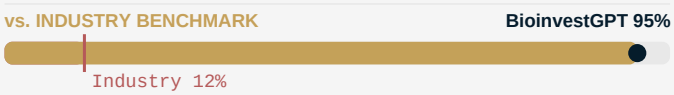
F1-Score

95%

Harmonic mean of Precision and Recall

`2×TP / (2×TP + FP + FN)`

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



++RELIABILITY GO/NO-GO reliability rate

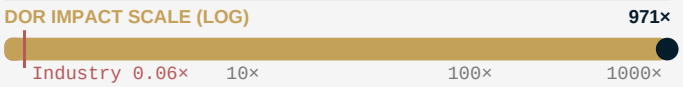
Diagnostic Odds Ratio (DOR)

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).

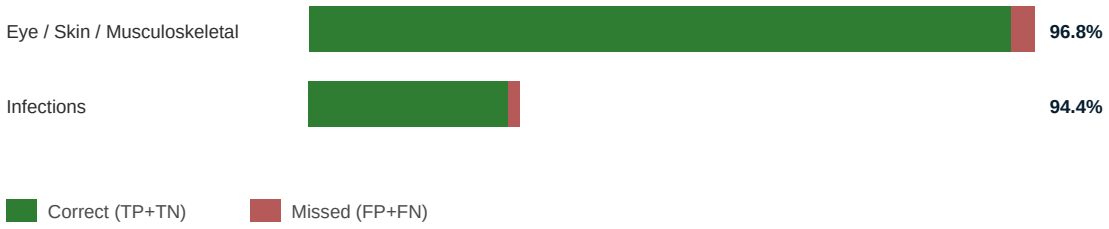
Therapeutic Area Breakdown

Infections, Eye/Skin/Muscul

Exhibit 1

Prediction accuracy remains consistently high across all therapeutic domains

BioinvestGPT's validation dataset spans 2 major therapeutic areas, demonstrating that predictive accuracy is not an artifact of concentration in any single domain.



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

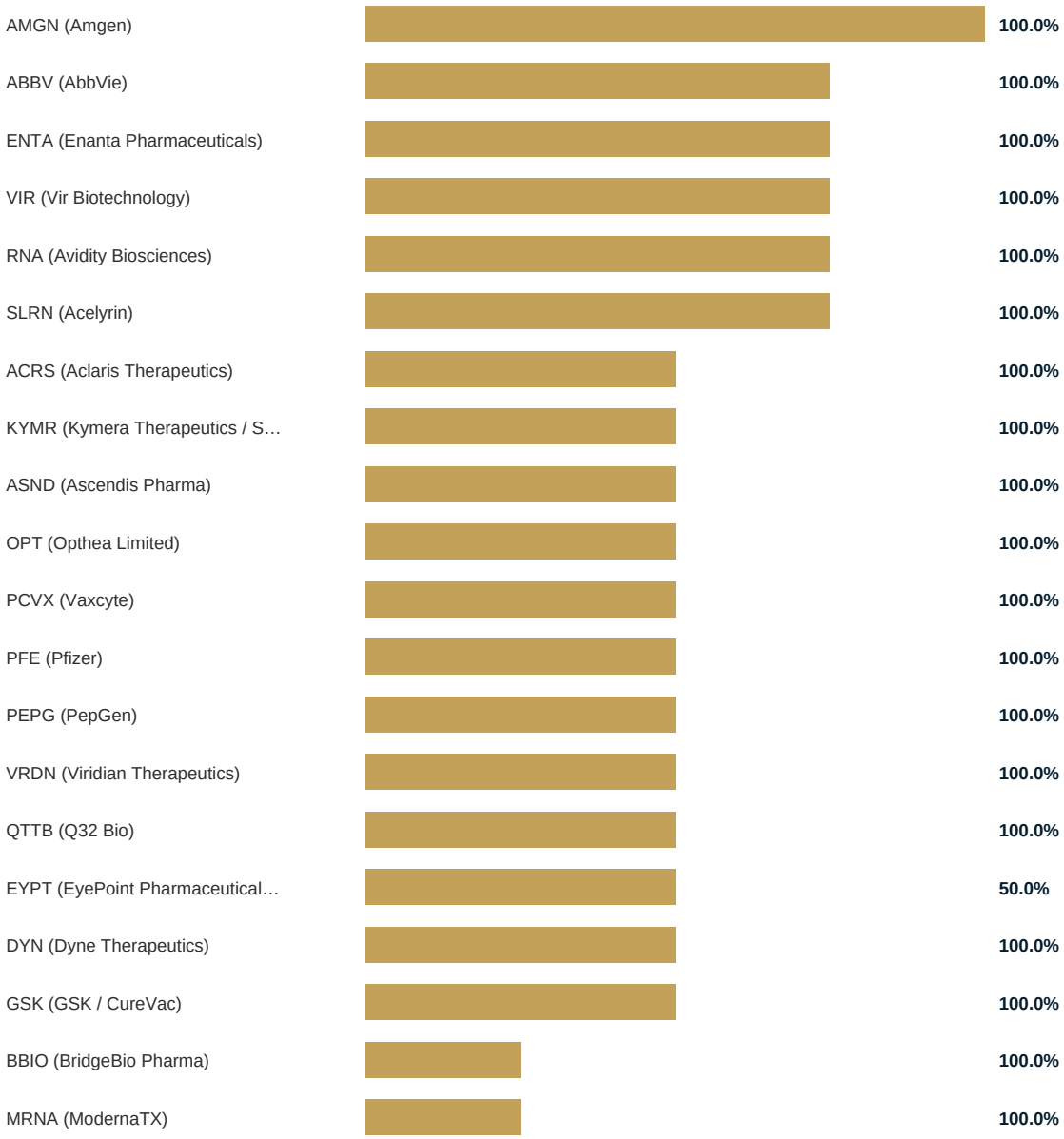
Sponsors Coverage Breakdown

Infections, Eye/Skin/Muscul

Exhibit 2

Validation spans 55 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: 55 | Average accuracy across top sponsors: 97.5%

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

Drug Innovation & Modality Coverage Breakdown

Infections, Eye/Skin/Muscul

Exhibit 3

Validated across 73 distinct drug assets spanning 10 modalities

DRUG CLASSIFICATION

FIRST-IN-CLASS

63

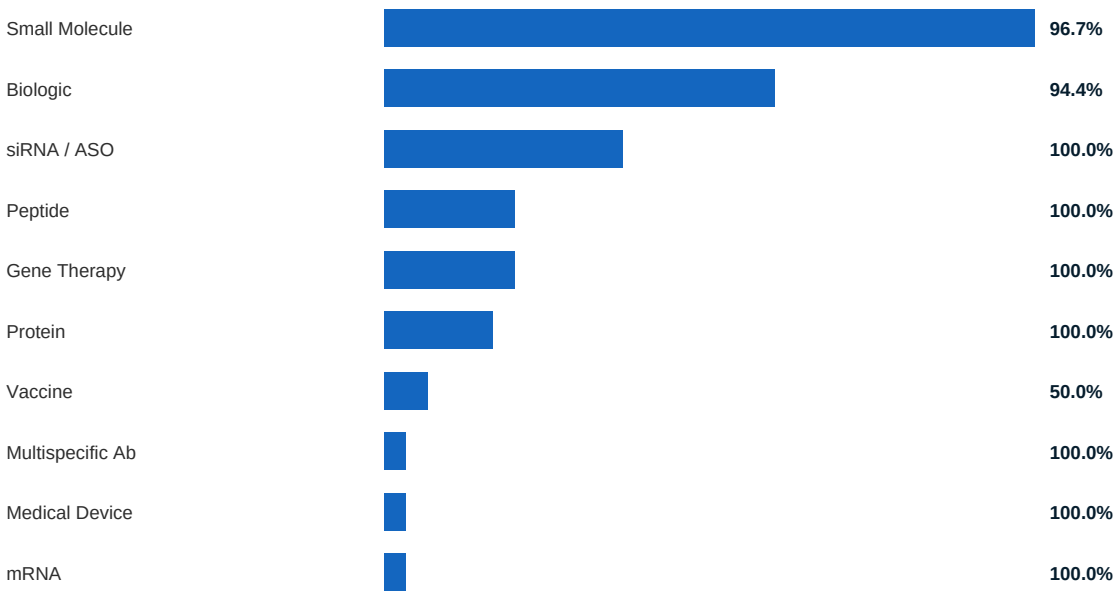
96.3% accuracy

BEST-IN-CLASS

17

96.3% accuracy

DRUG MODALITY DISTRIBUTION

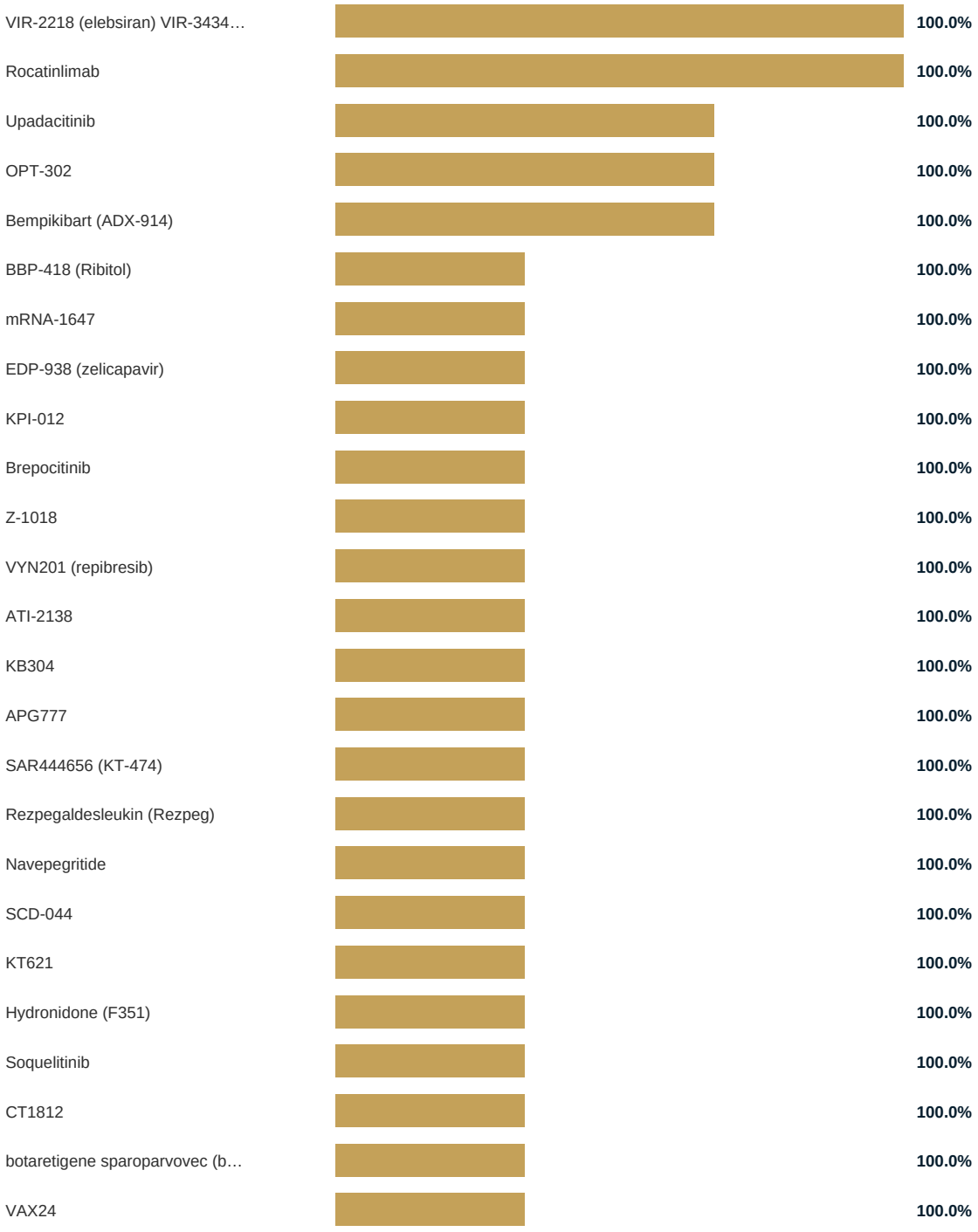


Drug Assets Coverage Breakdown

Infections, Eye/Skin/Muscul

Exhibit 4

Validated across 73 distinct drug assets with consistently high prediction accuracy



Total unique drug assets: 73 | 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.

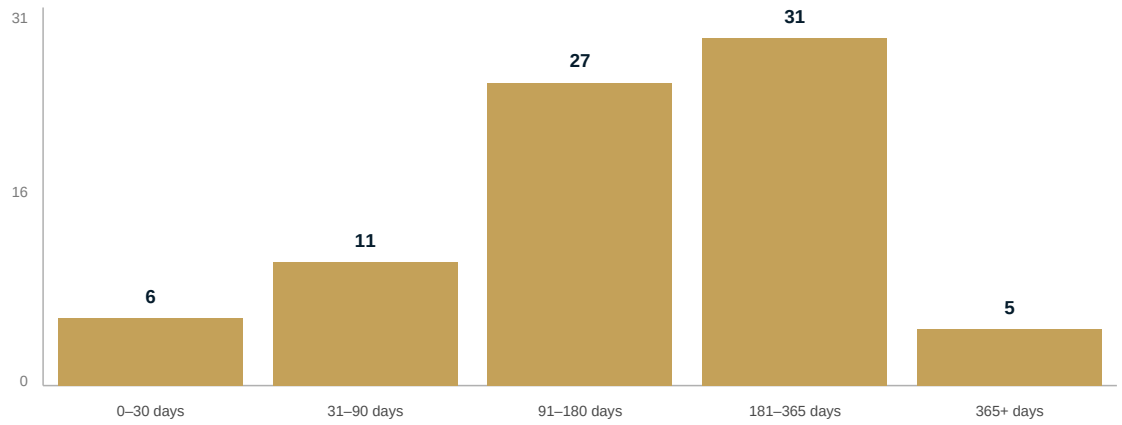
Temporal Integrity: Prospective Proof

Infections, Eye/Skin/Muscul

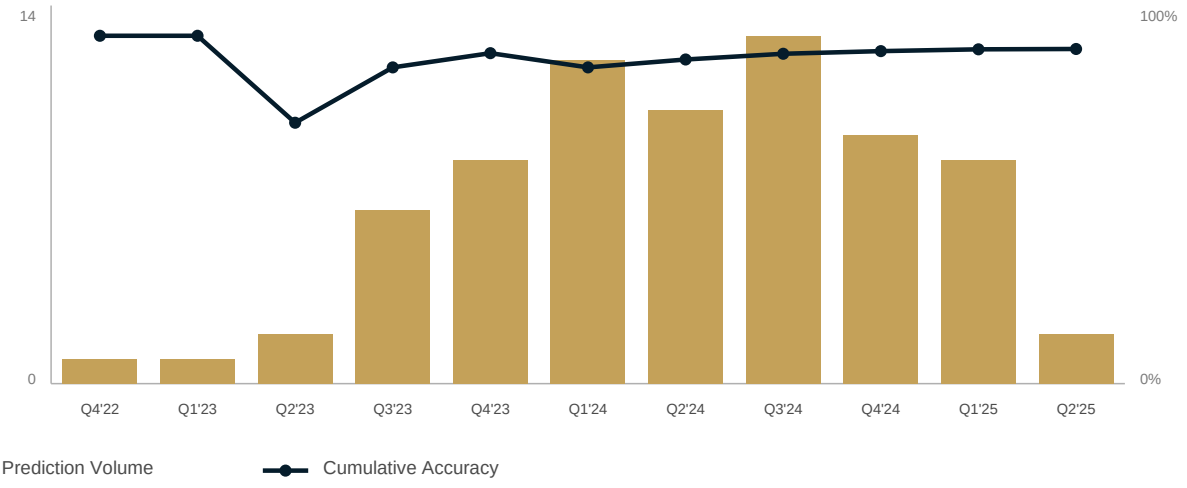
Exhibit 5

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

LEAD TIME DISTRIBUTION



QUARTERLY PREDICTION VOLUME & CUMULATIVE ACCURACY



All 80 predictions were certified ex-ante, with an average lead time of 185 days before clinical readout. This temporal integrity is cryptographically verifiable and eliminates any possibility of post-hoc fitting.

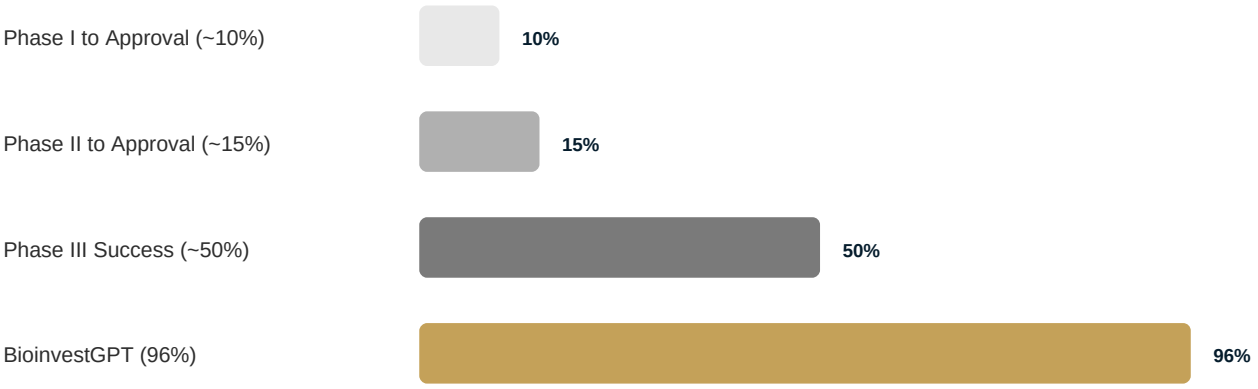
Competitive Benchmark Analysis

Infections, Eye/Skin/Muscul

Exhibit 6

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

CLINICAL DEVELOPMENT SUCCESS RATES



QUANTITATIVE BENCHMARK

Metric	BioinvestGPT	Industry Avg	Context
Accuracy	96.3%	~10-15%	Phase I-to-approval historical rate
Precision (PPV)	90.6%	~11%	Avg drug approval probability
NPV	100.0%	~60%	Combined Phase I–III attrition detection
F1-Score	95.1%	12%	Based on industry 10% nomination rate
DOR	971.3x	0.06x	Based on industry 10% nomination rate
Lead Time	185 days	0 days	Post-hoc industry standard

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

REDIRECTABLE R&D CAPITAL

$14.4B

48 of 48 NO-GO predictions validated × $300M avg trial cost

CAPTURED PORTFOLIO VALUE

$29.0B

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

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
1938	**Upadacitinib** **NCTID: NCT06118411** **Phase: Phase 3** **Class: Best-In-Class** **Modality: small molecule** **MoA: pan-JAK inhibitor with higher efficacy against JAK1** **Area: Skin and Connective Tissue Diseases** **Indication: Vitiligo** **Human Patients: 614** **Sponsor: AbbVie (ABBV)**	Date: 24 Feb 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in F-VASI75/T-VASI50 for both upadacitinib monotherapy and upadacitinib + NB-UVB combotherapy compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit F-VASI75/T-VASI50 for both upadacitinib monotherapy and upadacitinib + NB-UVB combotherapy moderately superior to ruxolitinib)	Readout: 29 Oct 2025 **Lead Time: 247 days in advance** Interpretation: Upadacitinib 15mg achieved statistically significant 13.5%-15.6% placebo-adjusted T-VASI50 improvement at week 48($p<0.05$); statistically significant 16.5%-19.3% placebo-adjusted F-VASI75 improvement at week 48 ($p<0.05$); and statistically significant 30.5%-35.4% placebo-adjusted F-VASI50 improvement at week 48 (p value undisclosed); no clinical data for ruxolitinib in refractory vitiligo available	Correct Prediction Conclusion: statistically significant and commercially sufficient (no approved SoC for refractory vitiligo) Classification: **True Positive (TP)**
1890	**BBP-418 (Ribitol)** **NCTID: NCT05775848** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: prodrug ribitol** **Area: Musculoskeletal Diseases** **Indication: Limb-Girdle Muscular Dystrophy Type 2I (LGMD2I)** **Human Patients: 81** **Sponsor: BridgeBio Pharma (BBIO)**	Date: 26 Jan 2025 Quarter: Q2'25 Batch 6 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in NSAD/10MWR compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in NSAD/10MWR non-superior to FKRP gene therapy)	Readout: 27 Oct 2025 **Lead Time: 274 days in advance** Interpretation: BBP418 achieved 0.27m/s placebo-adjusted improvement in 100MTT ($p<0.0001$);which is below the MCID threshold (>=0.55m/s placebo-adjusted improvement in 100MTT; calculated using the 112.2(127.9) baseline 100MTT of patients in the FORTIFY trial (see add'l link below) and the 1/3 SD MCID definition (doi.org/10.1212/WNL.92.15_supplement.S33.003)	Correct Prediction Conclusion: statistically significant yet weak clinical benefit and commercially probably insufficient Classification: **True Negative (TN)**
843	**mRNA-1647** **NCTID: NCT05085366** **Phase: Phase 3** **Class: First-In-Class** **Modality: Vaccine** **MoA: mRNA vaccine for Cytomegalovirus** **Area: Infections** **Indication: Cytomegalovirus Infection** **Human Patients: 7454** **Sponsor: ModernaTX (MRNA)**	Date: 14 May 2024 Quarter: Q3'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 22 Oct 2025 **Lead Time: 526 days in advance** Interpretation: mRNA-1647 failed to meet the primary efficacy endpoint of preventing CMV infection compared with placebo and further development has been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1036	**EDP-938 (zelicapavir)** **NCTID: NCT05568706** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: RSV N-protein inhibitor** **Area: Infections** **Indication: Respiratory Syncytial Virus (RSV)** **Human Patients: 186** **Sponsor: Enanta Pharmaceuticals (ENTA)**	Date: 10 May 2024 Quarter: Q3'24 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with non-superior-to-palivizumab efficacy)	Readout: 29 Sep 2025 **Lead Time: 507 days in advance** Interpretation: zelicapavir failed to meet the primary endpoint in the time to resolution of the LRTD subset of four symptoms while meeting multiple secondary endpoints in PGI-S score and 2-day faster resolution	Correct Prediction Conclusion: statistically partially insignificant and commercially probably insufficient Classification: **True Negative (TN)**
1947	**KPI-012** **NCTID: NCT05727878** **Phase: Phase 2** **Class: First-In-Class** **Modality: protein biologic** **MoA: human bone marrow mesenchymal stem cell secretome** **Area: Eye Diseases** **Indication: Persistent corneal epithelial defect (PCED)** **Human Patients: 103**	Date: 27 Mar 2025 Quarter: Q2'25 Batch 13a Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in complete healing compared with placebo featuring a negative dose-response relationship) Commercial: partial FAILURE (commercially insufficient clinical benefit in complete healing; yet there is no FDA-approved treatment for PCED)	Readout: 29 Sep 2025 **Lead Time: 186 days in advance** Interpretation: KPI-012 failed to meet the primary efficacy endpoint in complete healing compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Kala Bio (KALA)			
1132	**Brepocitinib** **NCTID: NCT05437263** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: JAK1/TYK2 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Dermatomyositis** **Human Patients: 241** **Sponsor: Roivant Sciences (ROIV)**	Date: 14 May 2025 Quarter: Q3'25 Batch 8 Technical: partial SUCCESS (statistically significant additive clinical benefit in TIS score compared with placebo for previously untreated patients) partial FAILURE (statistically insignificant clinical benefit in TIS score compared with placebo for previously treated patients) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit in TIS score compared with placebo for previously untreated patients) partial FAILURE (commercially insufficient clinical benefit in TIS score compared with placebo for previously treated patients)	Readout: 17 Sep 2025 **Lead Time: 126 days in advance** Interpretation: brepocitinib 30mg achieved 15.3 placebo-adjusted improvement in TIS at week 52 (p=0.0006)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1996	**Z-1018** **NCTID: NCT06569823** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: Vaccine** **MoA: subunit vaccine comprising gE antigen with CpG 1018 adjuvant** **Area: Infections** **Indication: Shingles** **Human Patients: 764** **Sponsor: Dynavax Technologies (DVAX)**	Date: 3 May 2025 Quarter: Q3'25 Batch 3 Technical: FAILURE (statistically significant clinical benefit in immunogenicity superior to placebo yet non-superior to Shingrix) Commercial: FAILURE (commercially insufficient clinical benefit in herpes zoster risk reduction moderately inferior to Shingrix)	Readout: 21 Aug 2025 **Lead Time: 110 days in advance** Interpretation: Z-1018 achieved a composite vaccine response rate of 89.7%; slightly inferior to Shingrix that achieved a composite vaccine response rate of 90.3% in the same trial	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to Shingrix) Classification: **True Negative (TN)**
1944	**VYN201 (repibresib)** **NCTID: NCT06493578** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: BET inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Non-segmental Vitiligo** **Human Patients: 200** **Sponsor: Vyne Therapeutics (VYNE)**	Date: 27 Mar 2025 Quarter: Q2'25 Batch 12b Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in F-VASI50/T-VASI50 compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in F-VASI50/T-VASI50 inferior to baricitinib/ruxolitinib/upadacitinib)	Readout: 30 Jul 2025 **Lead Time: 125 days in advance** Interpretation: repibresib failed to achieve the primary endpoint in F-VASI50 at week 24	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1937	**Upadacitinib** **NCTID: NCT06012240** **Phase: Phase 3** **Class: Best-In-Class** **Modality: small molecule** **MoA: pan-JAK inhibitor with higher efficacy against JAK1** **Area: Skin and Connective Tissue Diseases** **Indication: Alopecia Areata** **Human Patients: 1500** **Sponsor: AbbVie (ABBV)**	Date: 24 Feb 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in SALT<=20 compared with placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in SALT<=20/SALT<=10 moderately superior to baricitinib)	Readout: 30 Jul 2025 **Lead Time: 156 days in advance** Interpretation: Upadacitinib achieved 50.9% placebo-adjusted SALT20 response at week 24; moderately superior to ritlecitinib that achieved 29.1% placebo-adjusted SALT20 response at week 24 (see add'l link below) and moderately superior to baricitinib that achieved 28% placebo-adjusted SALT20 response at week 24 (see DOI-10.1056/NEJMoa2110343)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1844	**ATI-2138** **NCTID: NCT06585202** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: oral anti-ITK and anti-JAK3**	Date: 10 Nov 2024 Quarter: Q1'25 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo)	Readout: 29 Jul 2025 **Lead Time: 261 days in advance** Interpretation: ATI2138 achieved 77.1% mean EASI score improvement at week 12 (p<0.001); superior to dupilumab's 67.5% mean	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	dual inhibitor **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Atopic Dermatitis** **Human Patients: 14** **Sponsor: Aclaris Therapeutics (ACRS)**	Commercial: SUCCESS (commercially sufficient clinical benefit in EASI75 superior to dupilumab and superior to upadacitinib)	EASI score improvement at week 12 (see add'l link below); and superior to upadacitinib's 69.2% mean EASI score improvement at week 12-16 (see DOI-10.1016/j.ad.2024.10.067)	
2020	**KB304** **NCTID: NCT06724900** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: gene therapy** **MoA: HSV1 gene therapy delivering COL3A1 and ELN transgenes** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Wrinkles of the Décolleté** **Human Patients: 376** **Sponsor: Krystal Biotech (KRYS)**	Date: 13.May.25 Quarter: Q3'25 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit in wrinkle reduction compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit in wrinkle reduction slightly inferior to KB301)	Readout: 24 Jul 2025 Lead Time: — Interpretation: KB304 achieved numerically higher subject-reported >=1 point GAIS improvement at three months (72.7% vs 14.3%; no p-value reported); no data reported for improvements in wrinkle severity such as JDWS	Correct Prediction Conclusion: statistically maybe insignificant (no p-value reported) and commercially TBD Classification: **True Negative (TN)**
1882	**APG777** **NCTID: NCT06395948** **Phase: Phase 2** **Class: Best-In-Class** **Modality: monoclonal antibody** **MoA: YTE-and-LALA-modified anti-IL13 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: moderate-to-severe Atopic Dermatitis** **Human Patients: 431** **Sponsor: Apogee Therapeutics (APGE)**	Date: 23 Jan 2025 Quarter: Q2'25 Batch 5 Technical: SUCCESS (statistically significant clinical benefit in EASI75 compared with placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in EASI75 at least numerically superior to lebrikizumab yet still inferior to upadacitinib)	Readout: 7 Jul 2025 **Lead Time: 165 days in advance** Interpretation: APG777 achieved 42.3% placebo-adjusted EASI75 at week 16 ($p < 0.001$); numerically superior to lebrikizumab's 38% placebo-adjusted EASI75 at week 16 averaged from two phase 3 trials (see 10.1056/NEJMoa2206714); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
1822	**SAR444656 (KT-474)** **NCTID: NCT06058156** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: E3ligase-binding IRAK4 degrader** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Atopic Dermatitis** **Human Patients: 70** **Sponsor: Kymera Therapeutics / Sanofi (KYMR / SNY)**	Date: 4 Nov 2024 Quarter: Q1'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-superior to upadacitinib)	Readout: 25 Jun 2025 **Lead Time: 233 days in advance** Interpretation: SAR444656's further development is discontinued	Correct Prediction Conclusion: statistically TBD and commercially insufficient Classification: **True Negative (TN)**
1820	**Rezpegaldesleukin (Rezpeg)** **NCTID: NCT06136741** **Phase: Phase 2** **Class: First-In-Class** **Modality: PEGylated peptide** **MoA: pegylated recombinant protein IL2 agonist** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Atopic Dermatitis** **Human Patients: 396** **Sponsor: Nektar Therapeutics (NKTR)**	Date: 3 Nov 2024 Quarter: Q1'25 Batch 6 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab or upadacitinib)	Readout: 24 Jun 2025 **Lead Time: 233 days in advance** Interpretation: rezpegaldesleukin achieved 25% placebo-adjusted EASI75 at week 16; inferior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see DOI-10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to both dupilumab and upadacitinib) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
1776	**Navepegritide** **NCTID: NCT06433557** **Phase: Phase 2** **Class: Best-In-Class** **Modality: peptide** **MoA: long-lasting c-type natriuretic peptide** **Area: Musculoskeletal Diseases** **Indication: children with achondroplasia (ACH)** **Human Patients: 22** **Sponsor: Ascendis Pharma (ASND)**	Date: 29 Aug 2024 Quarter: Q4'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit in AGV against placebo) Commercial: SUCCESS (commercially sufficient additive clinical benefit in AGV at least numerically superior to vosoritide)	Readout: 9 Jun 2025 **Lead Time: 284 days in advance** Interpretation: navepegritide + lonapegsomatropin achieved 9.14cm/year mean AGV for treatment-naive patients; superior to vosoritide's 4cm/year mean AGV for treatment-naive patients (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: **True Positive (TP)**
1687	**SCD-044** **NCTID: NCT04684485** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: highly selective second-gen S1PR1 agonist** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Atopic Dermatitis** **Human Patients: 250** **Sponsor: Sun Pharmaceutical (SUNPHARMA)**	Date: 18 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab and non-superior to baricitinib)	Readout: 2 Jun 2025 **Lead Time: 319 days in advance** Interpretation: SCD044 failed to achieve statistically significant clinical benefit in EASI75 compared with placebo; further development discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1823	**KT621** **NCTID: NCT06673667** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: E3ligase-binding STAT6 degrader** **Area: Skin and Connective Tissue Diseases** **Indication: moderate-to-severe atopic dermatitis** **Human Patients: 120** **Sponsor: Kymera Therapeutics (KYMR)**	Date: 27 Mar 2025 Quarter: Q2'25 Batch 12b Technical: partial SUCCESS (statistically significant yet weak clinical benefit in EASI75 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 at most slightly superior to dupilumab and inferior to upadacitinib)	Readout: 2 Jun 2025 **Lead Time: 67 days in advance** Interpretation: KT621 achieved median TARC reduction up to 37% at day 14; inferior to dupilumab's 55%-65% TARC reduction at day 14 (see add'l link below)	Correct Prediction Conclusion: statistically significant (yet weak efficacy) and commercially probably insufficient (inferior to dupilumab) Classification: **True Negative (TN)**
1419	**Quadrivalent modRNA vaccine** **NCTID: NCT05540522** **Phase: Phase 3** **Class: First-In-Class** **Modality: Vaccine** **MoA: Quadrivalent anti-hemagglutinin mRNA vaccine** **Area: Infections** **Indication: Influenza** **Human Patients: 45789** **Sponsor: Pfizer (PFE)**	Date: 15 Jan 2024 Quarter: Q1'24 bespoke Batch Q1'24 bespoke Technical: partial SUCCESS (statistically significant clinical benefit for A/H3N2 for >=65 ysd participants) partial FAILURE (statistically insignificant clinical benefit for B/Victoria; B/Yamagata; and A/H1N1 for >=65 ysd participants) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit with non-inferior-to-SoC anti-ILI efficacy for A/H3N2 for >=65 ysd participants) partial FAILURE (commercially insufficient clinical benefit with inferior-to-adjuvanted SoC anti-ILI efficacy for B/Victoria; B/Yamagata; and A/H1N1 for >=65 ysd participants)	Readout: 28 May 2025 **Lead Time: 499 days in advance** Interpretation: qIRV failed to achieve non-inferiority in anti-ILI efficacy compared with SoC licensed QIV for people >= 65 years	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1801	**Hydronidone (F351)** **NCTID: NCT05115942** **Phase: Phase 3** **Class: First-In-Class**	Date: 15 Oct 2024 Quarter: Q1'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in fibrosis	Readout: 22 May 2025 **Lead Time: 219 days in advance** Interpretation: hydronidone achieved 23% placebo-adjusted fibrosis	Correct Prediction Conclusion: statistically significant and commercially sufficient

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Modality: small molecule **MoA: SMAD7 agonist** **Area: Infections** **Indication: Chronic Viral Hepatitis B** **Human Patients: 248** **Sponsor: Gyre Therapeutics (GYRE)**	improvement against placebo despite negative dose-response relationship for high doses) Commercial: SUCCESS (commercially sufficient clinical benefit in fibrosis improvement superior to tirzepatide)	improvement at week 52; superior to tirzepatide's 21% delta at week 52 (see add'l link below) and efruxifermin's 21% delta at week 24 (see 10.1001/jamanetworkopen.2022.31982)	Classification: **True Positive (TP)**
444	**VIR-2218 (elebsiran) VIR-3434 (tobevibart)** **NCTID: NCT04856085** **Phase: Phase 2** **Class: First-In-Class** **Modality: siRNA and monoclonal antibody (mAb)** **MoA: anti-HBx-HBV siRNA and anti-HBsAg mAb inhibitor** **Area: Infections** **Indication: Chronic hepatitis B viral infection** **Human Patients: 244** **Sponsor: Vir Biotechnology (VIR)**	Date: 14 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in TEAE and HBsAg against placebo for which VIR-2218 is non-superior-non-inferior to bepirovirsen) Commercial: FAILURE (commercially insufficient clinical benefit in HBV DNA suppression non-superior to SoC)	Readout: 9 May 2025 **Lead Time: 268 days in advance** Interpretation: VIR2218 + VIR3434 achieved functional cure (HBsAg absence and HBV DNA absence) in 4% participants at week 24; inferior to bepirovirsen that achieved functional cure in 10% participants at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (non-superior to bepirovirsen) Classification: **True Negative (TN)**
1797	**Soquelitinib** **NCTID: NCT06345404** **Phase: Phase 1** **Class: First-In-Class** **Modality: small molecule** **MoA: anti-ITK inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: atopic dermatitis** **Human Patients: 64** **Sponsor: Corvus Pharmaceuticals (CRVS)**	Date: 10 Nov 2024 Quarter: Q1'25 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in EASI75 superior to adalimumab and non-inferior to upadacitinib)	Readout: 8 May 2025 **Lead Time: 179 days in advance** Interpretation: soquelitinib achieved 63% placebo-adjusted EASI75 at week 4; superior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see add'l link below); and non-inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see 10.1016/S0140-6736(21)00588-2)	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferior to upadacitinib) Classification: **True Positive (TP)**
1620	**CT1812** **NCTID: NCT05893537** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: allosteric sigma-2 receptor antagonist** **Area: Eye Diseases** **Indication: geographic atrophy (GA) secondary to dry age-related macular degeneration** **Human Patients: 100** **Sponsor: Cognition Therapeutics (CGTX)**	Date: 15 May 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 8 May 2025 **Lead Time: 358 days in advance** Interpretation: CT1812 achieved 28.6% slower GA lesion growth compared with placebo yet not statistically significant; and CT1812 discontinued further development in GA (see add'l link below)	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: **True Negative (TN)**
1850	**botaretigene sparoparvovec (bota-vec)** **NCTID: NCT04671433** **Phase: Phase 3** **Class: First-In-Class** **Modality: gene therapy** **MoA: AAV5 gene therapy delivering RPGR transgene** **Area: Eye Diseases** **Indication: X-linked retinitis pigmentosa (XLRP)** **Human Patients: 97** **Sponsor: Johnson & Johnson (JNJ)**	Date: 3 Dec 2024 Quarter: Q1'25 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in VMA/BCVA against placebo) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in VMA/BCVA superior to 4D-125; given that no gene therapy has been approved for XLRP and Elevidys's label expansion has been approved for DMD despite very weak efficacy data)	Readout: 5 May 2025 **Lead Time: 153 days in advance** Interpretation: bota-vec failed to achieve statistically significant improvement in vision-guided mobility compared with placebo	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
1199	**OPT-302** **NCTID: NCT04757610** **Phase: Phase 3** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: recombinant fusion protein as anti-VEGFC and anti-VEGFD trap** **Area: Eye Diseases** **Indication: Neovascular Age-related Macular Degeneration (nAMD)** **Human Patients: 986** **Sponsor: Opthea Limited (OPT)**	Date: 14 Jan 2025 Quarter: Q2'25 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in BCVA) Commercial: FAILURE (commercially insufficient additive clinical benefit in BCVA)	Readout: 31 Mar 2025 **Lead Time: 76 days in advance** Interpretation: OPT302 + ranibizumab failed to achieve statistical significance in BCVA compared with ranibizumab monotherapy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1599	**VAX24** **NCTID: NCT05844423** **Phase: Phase 2** **Class: First-In-Class** **Modality: Vaccine** **MoA: 24-valent pneumococcal conjugate antigen-based vaccine** **Area: Infections** **Indication: invasive pneumococcal disease prevention** **Human Patients: 802** **Sponsor: Vaxcyte (PCVX)**	Date: 12 May 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant clinical benefit non-inferior-and-non-superior-to PCV15/PCV20) Commercial: SUCCESS (commercially sufficient clinical benefit non-inferior-and-non-superior-to PCV15/PCV20)	Readout: 31 Mar 2025 **Lead Time: 323 days in advance** Interpretation: VAX24 mid-dose met the non-inferiority criteria on relative seroconversion rates compared with PCV20	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferior-and-non-superior) Classification: **True Positive (TP)**
1200	**OPT-302** **NCTID: NCT04757636** **Phase: Phase 3** **Class: First-In-Class** **Modality: fusion protein biologic** **MoA: recombinant fusion protein as anti-VEGFC and anti-VEGFD trap** **Area: Eye Diseases** **Indication: Neovascular Age-related Macular Degeneration (nAMD)** **Human Patients: 998** **Sponsor: Opthea Limited (OPT)**	Date: 14 Jan 2025 Quarter: Q2'25 Batch 2 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in BCVA) Commercial: FAILURE (commercially insufficient additive clinical benefit in BCVA)	Readout: 24 Mar 2025 **Lead Time: 69 days in advance** Interpretation: OPT302 + aflibercept failed to achieve statistical significance in BCVA compared with aflibercept mono therapy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1000	**AOC1044 (del-zota)** **NCTID: NCT05670730** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: antibody-conjugated antisense oligonucleotide ASO** **MoA: antibody–oligonucleotide conjugate that binds the transferrin receptor 1 (TfR1) to deliver a PMO into muscle cells; inducing exon 44 skip, restoring functional dystrophin synthesis** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 70** **Sponsor: Avidity Biosciences (RNA)**	Date: 7 Jul 2024 Quarter: Q3'24 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in dystrophin protein level) Commercial: FAILURE (commercially insufficient clinical benefit in the registrational endpoint 6MWD non-superior and non-inferior to DYNE251 or SRP5051)	Readout: 17 Mar 2025 **Lead Time: 253 days in advance** Interpretation: del-zota achieved a statistically significant increase of 25% dystrophin production and 40% in exon 44 skipping; 6MWD data immature	Correct Prediction Conclusion: statistically significant (dystrophin) and commercially TBD (6MWD) Classification: **True Positive (TP)**
1860	**Rocatinlimab** **NCTID: NCT05724199** **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-OX40 inhibitor**	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit in vIGA-AD/EASI75 against placebo with positive dose-response	Readout: 8 Mar 2025 **Lead Time: 91 days in advance** Interpretation: rocatinlimab (low dose) achieved 30.4% placebo-adjusted EASI75 at week 24; inferior to dupilumab nearly 40%	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (inferior to upadacitinib) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Skin and Connective Tissue Diseases **Indication: Moderate-to-sever Atopic Dermatitis** **Human Patients: 746** **Sponsor: Amgen (AMGN)**	relationship) Commercial: partial SUCCESS (commercially sufficient yet moderate additive clinical benefit in vIGA-AD/ EASI75 (higher dose); superior to dupilumab +TCS/TCI yet inferior to upadacitinib +TCS/TCI)	placebo-adjusted EASI75 at week 16 (see 10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	
1859	**Rocatinlimab** **NCTID: NCT05398445** **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-OX40 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate-to-sever Atopic Dermatitis** **Human Patients: 769** **Sponsor: Amgen (AMGN)**	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant clinical benefit in vIGA-AD/EASI75 against placebo with positive dose-response relationship) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit in vIGA-AD/ EASI75 (higher dose); superior to dupilumab yet inferior to upadacitinib)	Readout: 8 Mar 2025 **Lead Time: 91 days in advance** Interpretation: rocatinlimab achieved 29.5% placebo-adjusted EASI75 at week 24; inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially maybe insufficient (inferior to upadacitinib) Classification: **True Negative (TN)**
1558	**PGN-EDODM1** **NCTID: NCT06204809** **Phase: Phase 1** **Class: First-In-Class** **Modality: peptide-conjugated antisense oligonucleotide ASO** **MoA: anti-DMPK-CUG-repeats-specific oligonucleotide** **Area: Musculoskeletal Diseases** **Indication: Myotonic Dystrophy Type 1** **Human Patients: 32** **Sponsor: PepGen (PEPG)**	Date: 24 Apr 2024 Quarter: Q3'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in spliceopathy) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit with superior-to-AOC1001 efficacy in terms of vHOT and muscle strength despite non-superior-to-AOC1001 toxicity)	Readout: 24 Feb 2025 **Lead Time: 306 days in advance** Interpretation: PGN-EDODM1 achieved 29.1% mean splicing correction without improved functional outcomes at day 28 (trends only)	Correct Prediction Conclusion: statistically significant (splicing correction) and commercially maybe sufficient yet weak (functional outcome) Classification: **True Negative (TN)**
1808	**Imvotamab** **NCTID: NCT06524687** **Phase: Phase 1** **Class: First-In-Class** **Modality: bispecific antibody** **MoA: anti-CD3 anti-CD20 T-cell engager** **Area: Musculoskeletal Diseases** **Indication: Idiopathic Inflammatory Myopathies** **Human Patients: 2** **Sponsor: IGM Biosciences (IGMS)**	Date: 26 Oct 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in MMT8 against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in MMT8)	Readout: 9 Jan 2025 **Lead Time: 75 days in advance** Interpretation: Imvotamab failed to demonstrate sufficient efficacy and further development discontinued accordingly	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1449	**daxdilimab** **NCTID: NCT05368103** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-ILT7 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Alopecia Areata** **Human Patients: 30** **Sponsor: Amgen (AMGN)**	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 7 Jan 2025 **Lead Time: 337 days in advance** Interpretation: daxdilimab achieved 13.3% SALT20 response at week 24; which would be inferior to ritlecitinib that achieved 29.1% placebo-adjusted SALT20 response at week 24 (see the add'l link below); Further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant (no placebo arm) and commercially insufficient Classification: **True Negative (TN)**
1251	**Sevasemten (EDG-5506)** **NCTID: NCT05291091** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: oral selective fast skeletal**	Date: 6 Aug 2024 Quarter: Q4'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in TNNI2) Commercial: FAILURE (commercially	Readout: 16 Dec 2024 **Lead Time: 132 days in advance** Interpretation: sevasemten achieved 77% reduction in plasma TNNI2 ($p<0.001$); sevasemten failed to achieved statistically significant	Correct Prediction Conclusion: statistically significant (TNNI2) and commercially insufficient (NSAA) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	muscle myosin inhibitor **Area: Musculoskeletal Diseases** **Indication: Becker Muscular Dystrophy** **Human Patients: 170** **Sponsor: Edgewise Therapeutics (EWTX)**	insufficient clinical benefit in either NSAA or 6MWD)	improvement in NSAA (p=0.16).	
1467	**veligrotug (VRDN-001)** **NCTID: NCT06021054** **Phase: Phase 3** **Class: Best-In-Class** **Modality: monoclonal antibody** **MoA: anti-IGF1R mAb inhibitor** **Area: Eye Diseases** **Indication: Chronic Thyroid Eye Disease** **Human Patients: 188** **Sponsor: Viridian Therapeutics (VRDN)**	Date: 14 Feb 2024 Quarter: Q4'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient clinical benefit non-superior to Tepezza)	Readout: 16 Dec 2024 **Lead Time: 306 days in advance** Interpretation: veligrotug achieved 48% placebo-adjusted PRR at week 15; non-superior to teprotumumab (Tepezza) that achieved 65% placebo-adjusted PRR at week 15 (DOI-10.1056/NEJMoa1910434); veligrotug further achieved 31% placebo-adjusted diplopia responder rate at week 15 (p=0.0006); non-superior to teprotumumab that achieved 48% placebo-adjusted diplopia responder rate at week 15 (DOI-10.1056/NEJMoa1910434)	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (non-superior to teprotumumab) Classification: **True Positive (TP)**
1387	**ANB032** **NCTID: NCT05935085** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-BTLA mAb agonist** **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis** **Human Patients: 160** **Sponsor: AnaptysBio (ANAB)**	Date: 30 Aug 2024 Quarter: Q4'24 Batch 15 Technical: partial SUCCESS (statistically significant yet weak clinical benefit in EASI75) Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 non-superior to dupilumab inferior to upadacitinib/NM26)	Readout: 11 Dec 2024 **Lead Time: 103 days in advance** Interpretation: ANB032 failed to achieve achieved statistical significance in placebo-adjusted EASI75 at week 14	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1187	**izokibep** **NCTID: NCT05384249** **Phase: Phase 2** **Class: Best-In-Class** **Modality: small protein scaffold-based biologic** **MoA: IL-17A Inhibitior** **Area: Eye Diseases** **Indication: uveitis** **Human Patients: 96** **Sponsor: ACELYRIN (SLRN)**	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in time to treatment failure and BCVA compared with corticosteroids alone) Commercial: FAILURE (commercially insufficient additive clinical benefit in time to treatment failure and BCVA inferior to adalimumab + corticosteroids)	Readout: 10 Dec 2024 **Lead Time: 3 days in advance** Interpretation: izokibep failed to achieve statistical significance in the primary efficacy endpoint of time to treatment failure and secondary efficacy endpoint BCVA	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1716	**Bempikibart (ADX-914)** **NCTID: NCT06018428** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-IL7Ralpha mAb inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Severe Alopecia Areata** **Human Patients: 40** **Sponsor: Q32 Bio (QTTB)**	Date: 14 Aug 2024 Quarter: Q4'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in SALT score against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in SALT score inferior to baricitinib)	Readout: 10 Dec 2024 **Lead Time: 118 days in advance** Interpretation: bempikibart probably failed to achieve statistical significance in the primary efficacy endpoint SALT score at week 24 (16% vs 2% placebo with a p=0.045 after excluding three placebo patients)	Correct Prediction Conclusion: statistically probably significant and commercially probably insufficient Classification: **True Negative (TN)**
1715	**Bempikibart (ADX-914)** **NCTID: NCT05509023** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-IL7Ralpha mAb**	Date: 14 Aug 2024 Quarter: Q4'24 Batch 1 Technical: FAILURE (statistically insignificant clinical benefit in EASI75 against placebo)	Readout: 10 Dec 2024 **Lead Time: 118 days in advance** Interpretation: bempikibart failed to achieve statistical significance in the primary efficacy endpoint EASI at week 14	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	inhibitor **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis** **Human Patients: 102** **Sponsor: Q32 Bio (QTTB)**	Commercial: FAILURE (commercially insufficient clinical benefit in EASI75 inferior to dupilumab)		
1038	**zelicapavir (EDP-938)** **NCTID: NCT04816721** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: RSV nucleoprotein inhibitor** **Area: Infections** **Indication: respiratory syncytial virus (RSV)** **Human Patients: 96** **Sponsor: Enanta Pharmaceuticals (ENTA)**	Date: 10 May 2024 Quarter: Q3'24 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with non-superior-to-palivizumab efficacy)	Readout: 9 Dec 2024 **Lead Time: 213 days in advance** Interpretation: zelicapavir achieved statistical significance in primary and secondary virology endpoints compared with placebo (peak 0.7-1.4 log viral load decline compared with placebo); no efficacy endpoint data has been disclosed.	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for efficacy data) Classification: **True Positive (TP)**
445	**VIR-2218 (elebsiran) VIR-3434 (tobevibart)** **NCTID: NCT05461170** **Phase: Phase 2** **Class: First-In-Class** **Modality: siRNA and monoclonal antibody (mAb)** **MoA: anti-HBx-HBV siRNA and anti-HBsAg mAb inhibitor** **Area: Infections** **Indication: Chronic Hepatitis D Infection** **Human Patients: 124** **Sponsor: Vir Biotechnology (VIR)**	Date: 14 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in HDV RNA suppression against placebo for which VIR-2218 is non-superior-non-inferior to bepiroviren) Commercial: FAILURE (commercially insufficient clinical benefit in HDV RNA suppression non-superior to SoC)	Readout: 19 Nov 2024 **Lead Time: 97 days in advance** Interpretation: elebsiran + tobevibart achieved 41% HDV RNA TND at week 24; which is inferior to 46% HDV RNA TND at week 24 achieved by 10-mg bulevirtide + PEG IFN-alfa-2a (DOI-10.1056/NEJMoa2314134)	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
444	**VIR-2218 (elebsiran) VIR-3434 (tobevibart)** **NCTID: NCT04856085** **Phase: Phase 2** **Class: First-In-Class** **Modality: siRNA and monoclonal antibody (mAb)** **MoA: anti-HBx-HBV siRNA and anti-HBsAg mAb inhibitor** **Area: Infections** **Indication: Chronic hepatitis B viral infection** **Human Patients: 244** **Sponsor: Vir Biotechnology (VIR)**	Date: 14 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in TEAE and HBsAg against placebo for which VIR-2218 is non-superior-non-inferior to bepirovirsen) Commercial: FAILURE (commercially insufficient clinical benefit in HBV DNA suppression non-superior to SoC)	Readout: 15 Nov 2024 **Lead Time: 93 days in advance** Interpretation: elebsiran + tobevibart achieved 16% HBsAg loss and elebsiran + tobevibart + PEG-IFNalpha achieved 22% HBsAg loss; of which elebsiran's about 7% HBsAg loss (see the data in the add link) is non-superior to bepirovirsen's 9-10% HBsAg loss (N Engl J Med DOI- 10.1056/NEJMoa2210027)	Correct Prediction Conclusion: statistically significant (HBsAg loss) and commercially TBD (pending HBV DNA suppression data) Classification: **True Positive (TP)**
1217	**SRP-5051** **NCTID: NCT04004065** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: Menin-MLL1 inhibitor** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 62** **Sponsor: Sarepta Therapeutics (SRPT)**	Date: 11 Aug 2023 Quarter: 2H'23 Batch 12 Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin level) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD)	Readout: 6 Nov 2024 **Lead Time: 453 days in advance** Interpretation: SRP5051 resulted in a mean absolute dystrophin expression of 5.17% at week 28; yet its further development has been discontinued due to unremarkable benefit-risk data	Correct Prediction Conclusion: statistically partially significant (dystrophin expression) and commercially insufficient (weak efficacy) Classification: **True Negative (TN)**
1463	**EYP-1901** **NCTID: NCT06099184**	Date: 14 Feb 2024 Quarter: - Batch -	Readout: 28 Oct 2024 **Lead Time: 257 days in advance**	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 2 **Class: First-In-Class** **Modality: small molecule** **MoA: multi-kinase VEGFR/PDGFR inhibitor** **Area: Eye Diseases** **Indication: Diabetic Macular Edema** **Human Patients: 25** **Sponsor: EyePoint Pharmaceuticals (EYPT)**	Technical: SUCCESS (statistically significant clinical benefit non-inferior to aflibercept in BCVA) Commercial: SUCCESS (commercially sufficient clinical benefit non-inferior to long-lasting aflibercept)	Interpretation: EYP1901 achieved +9.9 letters in BCVA and 68 micron reduction in CST; superior to aflibercept's +3.2 letters in BCVA and 30.5 micron reduction in CST	and commercially sufficient Classification: **True Positive (TP)**
1589	**CLS-AX** **NCTID: NCT05891548** **Phase: Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: axitinib injectable suspension** **Area: Eye Diseases** **Indication: Wet Age-Related Macular Degeneration** **Human Patients: 60** **Sponsor: Clearside Biomedical (CLSD)**	Date: 10 May 2024 Quarter: Q3'24 Batch 4 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit in BCVA) Commercial: FAILURE (commercially insufficient clinical benefit with non-superior-to-long-lasting-aflibercept efficacy in BCVA)	Readout: 9 Oct 2024 **Lead Time: 152 days in advance** Interpretation: CLS-AX achieved -1.9 BCVA score at week 36 whereas aflibercept in the active control arm achieved +1.5 BCVA score at week 36 (p=0.243); showing that CLS-AX is non-superior to aflibercept.	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to aflibercept) Classification: **True Negative (TN)**
1590	**EDP-323** **NCTID: NCT06170242** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: RSV L-protein inhibitor** **Area: Infections** **Indication: RSV Infection** **Human Patients: 114** **Sponsor: Enanta Pharmaceuticals (ENTA)**	Date: 10 May 2024 Quarter: Q3'24 Batch 4 Technical: SUCCESS (statistically significant yet moderate clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with non-superior-to-palivizumab efficacy)	Readout: 26 Sep 2024 **Lead Time: 139 days in advance** Interpretation: EDP323 achieved 78%-66% reduction in total symptom score AUC (p<0.0001) featuring a negative dose-response relationship; without disclosure of RSV LRTD symptom resolution or all-cause mortality data.	Correct Prediction Conclusion: statistically significant (yet moderate benefit with negative dose-response relationship) and commercially TBD Classification: **True Positive (TP)**
1595	**WVE-N531** **NCTID: NCT04906460** **Phase: Phase 1 Phase 2** **Class: Best-In-Class** **Modality: siRNA** **MoA: stereopure exon 53 skpping antisense oligonucleotides** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 11** **Sponsor: Wave Life Sciences (WVE)**	Date: 12 May 2024 Quarter: Q3'24 Batch 6 Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin protein level) partial FAILURE (statistically insignificant clinical benefit in NSAA/10MRW/SV95C) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD non-superior and non-inferior to DYNE251 or SRP5051)	Readout: 24 Sep 2024 **Lead Time: 135 days in advance** Interpretation: a mean absolute dystrophin expression of 5.5%; which is relatively higher than competitor drugs.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically partially significant (dystrophin expression) and partially TBD (functional endpoints) and commercially TBD Classification: **True Positive (TP)**
1445	**Rocatinlimab** **NCTID: NCT05651711** **Phase: Phase 3** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: anti-OX40 mAb inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis** **Human Patients: 726** **Sponsor: Amgen (AMGN)**	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in EASI75 against placebo) Commercial: SUCCESS (commercially sufficient clinical benefit in EASI75; superior to dupilumab/lebrikizumab; non-superior-and-non-inferior to amlitelimab; yet inferior to upadacitinib)	Readout: 24 Sep 2024 **Lead Time: 45 days in advance** Interpretation: rocatinlimab achieved 19.1% placebo-adjusted EASI75 at week 24; inferior to dupilumab nearly 40% placebo-adjusted EASI75 at week 16 (see 10.1056/NEJMoa1610020); and inferior to upadacitinib's nearly 60% placebo-adjusted EASI75 at week 24 (see 10.1016/S0140-6736(21)00588-2).	Overall Correct Prediction Conclusion: statistically significant and commercially maybe sufficient Classification: **True Positive (TP)**
660	**TransCon CNP** **NCTID: NCT05598320**	Date: 29 Aug 2024 Quarter: Q4'24 Batch 14	Readout: 16 Sep 2024 **Lead Time: 18 days in advance**	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 2 Phase 3 **Class: First-In-Class** **Modality: peptide prodrug** **MoA: long-lasting c-type natriuretic peptide** **Area: Musculoskeletal Diseases** **Indication: Achondroplasia** **Human Patients: 84** **Sponsor: Ascendis Pharma (ASND)**	Technical: SUCCESS (statistically significant clinical benefit in AGV against placebo) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate clinical benefit in AGV inferior to vosoritide due to suboptimal dosage)	Interpretation: once-weekly TransCon CNP achieved an AGV with LS mean treatment difference 1.49 cm/year; which is lower than 1.57cm/year achieved by the once-daily SoC vosoritide.	and commercially maybe sufficient (weaker efficacy yet better adherence with once-weekly administration) Classification: **True Positive (TP)**
1629	**Losmapimod** **NCTID: NCT05397470** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: p38±/²-MAPK sma molecule inhibitor** **Area: Musculoskeletal Diseases** **Indication: Facioscapulohumeral Muscular Dystrophy (FSHD)** **Human Patients: 260** **Sponsor: Fulcrum Therapeutics (FULC)**	Date: 25 Jul 2024 Quarter: Q4'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in RWS) Commercial: FAILURE (commercially insufficient clinical benefitin RWS for patients that are not stratified by p38MAPK expression levels)	Readout: 12 Sep 2024 **Lead Time: 49 days in advance** Interpretation: losmapimod failed to meet RWS primary endpoint.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
906	**VRDN 001** **NCTID: NCT05176639** **Phase: Phase 3** **Class: Best-In-Class** **Modality: monoclonal antibody** **MoA: anti-IGF1R mAb inhibitor** **Area: Eye Diseases** **Indication: Thyroid Eye Disease (TED)** **Human Patients: 154** **Sponsor: Viridian Therapeutics (VRDN)**	Date: 14 Feb 2024 Quarter: Q2'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient clinical benefit non-superior to Tepezza)	Readout: 10 Sep 2024 **Lead Time: 209 days in advance** Interpretation: VRDN001 achieved 64% placebo-adjusted PRR at week 15 vs. 65% placebo-adjusted PRR at week 15 achieved by the SoC teprotumumab in NCT03298867.	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-superior to teprotumumab) Classification: **True Positive (TP)**
1253	**DYNE-251** **NCTID: NCT05524883** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: siRNA** **MoA: dystrophin exon 51 skipping Fab** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 88** **Sponsor: Dyne Therapeutics (DYN)**	Date: 21 Nov 2023 Quarter: Q1'24 Batch 7 Technical: partial SUCCESS (statistically significant clinical benefit in dystrophin protein level); partial FAILURE (statistically insignificant clinical benefit in NSAA/10MRW/FVC) Commercial: FAILURE (commercially insufficient clinical benefit in 6MWD)	Readout: 3 Sep 2024 **Lead Time: 287 days in advance** Interpretation: a mean absolute dystrophin expression of 3.71% of normal; yet weak functional efficacy(change from baseline in SV95C only meet EMA-defined minimal clinically important difference (MCID); whereas other functional efficacy endpoints NSAA/10MWR probably didn't reach MCID).	Overall Correct Prediction Conclusion: statistically partially significant (dystrophin expression) and partially insignificant (functional endpoints) and commercially probably insufficient (weak efficacy) Classification: **True Negative (TN)**
1598	**VAX-31** **NCTID: NCT06151288** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: vaccine** **MoA: 31-valent pneumococcal conjugate antigen-based vaccine** **Area: Infections** **Indication: invasive pneumococcal disease (IPD)** **Human Patients: 1015** **Sponsor: Vaxcyte (PCVX)**	Date: 12 May 2024 Quarter: Q3'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit non-inferior-and-non-superior-to PCV20) Commercial: SUCCESS (commercially sufficient clinical benefit non-inferior-and-non-superior-to PCV20)	Readout: 3 Sep 2024 **Lead Time: 114 days in advance** Interpretation: OPA response non-inferiority criteria met for all 20 serotypes against SoC PCV20 and regulatory immunogenicity met for all 31 serotypes.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
1675	**Reproxalap Ophthalmic Solution (0.25%) Vehicle ophthalmic solution**	Date: 11 Jul 2024 Quarter: Q3'24 Batch 16 Technical: SUCCESS (statistically	Readout: 8 Aug 2024 **Lead Time: 28 days in advance** Interpretation: statistically significant	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT06424444 **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: RASP inhibitor** **Area: Eye Diseases** **Indication: Dry Eye Disease** **Human Patients: 400** **Sponsor: Aldeyra Therapeutics (ALDX)**	significant yet weak clinical benefit in treating ocular discomfort) Commercial: partial SUCCESS (commercially maybe sufficient yet mixed clinical benefit in treating ocular symptoms)	(p=0.004 without improvement data released (usually a sign of not strong efficacy); yet commercially sufficient for an unsaturated market.	Classification: **True Positive (TP)**
1557	**PGN-EDO51** **NCTID: NCT06079736** **Phase: Phase 2** **Class: First-In-Class** **Modality: peptide-conjugated antisense oligonucleotide ASO** **MoA: EDO cell-penetrating peptide conjugated with dystrophin exon 51 skipping oligonucleotide** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 10** **Sponsor: PepGen (PEPG)**	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit in dystrophin protein level) Commercial: FAILURE (commercially insufficient clinical benefit in the registrational endpoint 6MWD non-superior-to and non-inferior-to SRP-5051)	Readout: 30 Jul 2024 **Lead Time: 98 days in advance** Interpretation: 5mg low-dose exon skipping level and dystrophin level comparable to SRP5051 20mg (NCT04004065).	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD (pending functional efficacy data) Classification: **True Positive (TP)**
861	**Barzolvolimab Matching Placebo** **NCTID: NCT05405660** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody** **MoA: KIT receptor tyrosine kinase inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Chronic Inducible Urticaria** **Human Patients: 196** **Sponsor: Celldex Therapeutics (CLDX)**	Date: 19 Aug 2023 Quarter: 2H'23 Batch 16 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 29 Jul 2024 **Lead Time: 345 days in advance** Interpretation: CDX0159 achieved 40.6% placebo-adjusted CR.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**
396	**HIL-214** **NCTID: NCT05281094** **Phase: Phase 2 Phase 3** **Class: First-In-Class** **Modality: virus-like particle vaccine** **MoA: norovirus bivalent GI.1/GII/4 VLP vaccine** **Area: Infections** **Indication: Norovirus** **Human Patients: 3085** **Sponsor: HilleVax (HLVX)**	Date: 14 Feb 2024 Quarter: Q2'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 8 Jul 2024 **Lead Time: 145 days in advance** Interpretation: endpoints not met.	Missed Prediction Note: due to suboptimal disease model of norovirus that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient Classification: **False Positive (FP)**
1001	**AOC 1020** **NCTID: NCT05747924** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small interfering RNA (siRNA) antisense oligonucleotide** **MoA: anti-DUX4 siRNA oligonucleotide** **Area: Musculoskeletal Diseases** **Indication: Facioscapulohumeral Muscular Dystrophy (FSHD)** **Human Patients: 72** **Sponsor: Avidity Biosciences (RNA)**	Date: 30 Nov 2023 Quarter: Q1'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 12 Jun 2024 **Lead Time: 195 days in advance** Interpretation: 50% mean reduction in DUX4-targeted genes; yet with statistically insignificant trends of functional improvement.	Correct Prediction Conclusion: statistically significant and commercially insufficient (weak functional efficacy) Classification: **True Negative (TN)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
1414	**PF-06939926** **NCTID: NCT04281485** **Phase: Phase 3** **Class: Best-In-Class** **Modality: gene therapy** **MoA: rAAV9 vector carrying a minidystrophin gene** **Area: Musculoskeletal Diseases** **Indication: Duchenne Muscular Dystrophy (DMD)** **Human Patients: 122** **Sponsor: Pfizer (PFE)**	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-SRP9001 efficacy)	Readout: 12 Jun 2024 **Lead Time: 149 days in advance** Interpretation: statistically insignificant for all primary/secondary endpoints.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient (SRP9001 at least meet some secondary endpoints) Classification: **True Negative (TN)**
1198	**Bemnifosbuvir Ruzasvir** **NCTID: NCT05904470** **Phase: Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: viral RNA polymerase inhibitor** **Area: Infections** **Indication: Chronic Hepatitis C Virus** **Human Patients: 275** **Sponsor: Atea Pharmaceuticals (AVIR)**	Date: 1 Dec 2023 Quarter: Q1'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 5 Jun 2024 **Lead Time: 187 days in advance** Interpretation: achieved 97% SVR12	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: **True Positive (TP)**
846	**EQ101** **NCTID: NCT05589610** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: tri-specific IL2/IL9/IL15 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Moderate to Severe Alopecia Areata** **Human Patients: 36** **Sponsor: Equillium (EQ)**	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 4 Jun 2024 **Lead Time: 107 days in advance** Interpretation: 20-29% <20 SALT score at week 24 achieved by EQ101) (vs 23% <20 SALT score at week 24 achieved by ritlectinib 50mg King et al. 2023 Lancet in NCT03732807).	Correct Prediction Conclusion: statistically significant and commercially sufficient (only one approved treatment so far) Classification: **True Positive (TP)**
1186	**Ionigutamab** **NCTID: NCT05683496** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: IGF1R inhibitor** **Area: Eye Diseases** **Indication: Thyroid Eye Disease (TED)** **Human Patients: 38** **Sponsor: Acelyrin (SLRN)**	Date: 20 Nov 2023 Quarter: 2H'23 Batch 29 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit non-superior to Tepezza)	Readout: 29 May 2024 **Lead Time: 191 days in advance** Interpretation: 50% and 25% placebo-adjusted reduction in proptosis and diplopia at week 6 (vs 49% and 46% placebo-adjusted reduction in proptosis and diplopia achieved by tepezza at week 6 in similar clinical settings Douglas et Al. 2020 NEJM).	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior) Classification: **True Negative (TN)**
1212	**RPT193** **NCTID: NCT05399368** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: oral CCR4 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis** **Human Patients: 229** **Sponsor: RAPT Therapeutics (RAPT)**	Date: 10 Aug 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 May 2024 **Lead Time: 273 days in advance** Interpretation: terminated due to clinical holds.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1142	**EYP-1901 Sham IVT**	Date: 14 Feb 2024	Readout: 6 May 2024	Missed Prediction

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05383209 **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: intravitreally delivered vorolanib** **Area: Eye Diseases** **Indication: Nonproliferative Diabetic Retinopathy** **Human Patients: 105** **Sponsor: EyePoint Pharmaceuticals (EYPT)**	Quarter: Q2'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit non-inferior to aflibercept in BCVA) Commercial: SUCCESS (commercially sufficient clinical benefit non-inferior to long-lasting aflibercept)	**Lead Time: 82 days in advance** Interpretation: DRSS>2 score primary endpoint not met.	Note: due to suboptimal modelling of non-proliferation diabetic retinopathy which has been permanently co… Conclusion: statistically insignificant and commercially insufficient Classification: **False Positive (FP)**
1486	**Flu mRNA** **NCTID: NCT05823974** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: mRNA medicine** **MoA: Multivalent anti-hemagglutinin mRNA vaccine** **Area: Infections** **Indication: Influenza** **Human Patients: 1256** **Sponsor: GSK / CureVac (GSK / CVAC)**	Date: 27 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically significant clinical benefit for A/H3N2 for >=65 ysd participants); partial FAILURE (statistically insignificant clinical benefit for B/Victoria; B/Yamagata; and A/H1N1 for >=65 ysd participants) Commercial: partial SUCCESS (commercially sufficient yet moderate clinical benefit with non-inferior-to-FDQ21A-NH anti-ILI efficacy for A/H3N2 for >=65 ysd participants); partial FAILURE (commercially insufficient clinical benefit with inferior-to-FDQ21A-NH anti-ILI efficacy for B/Victoria; B/Yamagata; and A/H1N1 for >=65 ysd participants)	Readout: 4 Apr 2024 **Lead Time: 37 days in advance** Interpretation: numerically higher geometric mean titers for influenza A in both young and elderly age groups and lower geometric mean titers for influenza B in both young and elederly age groups.	Correct Prediction Conclusion: statistically significant against placebo yet commercially insufficient (especially for influenza B as we accurately predicted) Classification: **True Negative (TN)**
900	**HepTcell** **NCTID: NCT04684914** **Phase: Phase 2** **Class: First-In-Class** **Modality: peptide drug** **MoA: HPV-derived peptides** **Area: Infections** **Indication: Chronic Hepatitis B** **Human Patients: 87** **Sponsor: Altimmune (ALT)**	Date: 20 Nov 2023 Quarter: Q1'24 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 27 Mar 2024 **Lead Time: 128 days in advance** Interpretation: terminated due to lack of efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1058	**Paltusotine** **NCTID: NCT05192382** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: SST2R agonist** **Area: Musculoskeletal Diseases** **Indication: Acromegaly** **Human Patients: 111** **Sponsor: Crinetics Pharmaceuticals (CRNX)**	Date: 14 Aug 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to octreotide)	Readout: 19 Mar 2024 **Lead Time: 218 days in advance** Interpretation: 56% patients achieved IGF1 level < 1.0% and -2.67 ASD score; sueprior to the SoC octreitide LAR achieved 23.3% patients achieved IGF1 level < 1.0% and -2.67 ASD score.	Correct Prediction Conclusion: statistical significant and commercially sufficient Classification: **True Positive (TP)**
717	**Lebrikizumab (LY3650150)** **NCTID: NCT05372419** **Phase: Phase 3** **Class: Best-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: IL-13 mAb inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis and Skin of Color** **Human Patients: 80**	Date: 26 Nov 2022 Quarter: - Batch - Technical: SUCCESS Commercial: SUCCESS	Readout: 11 Mar 2024 **Lead Time: 471 days in advance** Interpretation: 68% EASI75 and 46% EASI90 55% itch reduction and 39% clear of skin; which is superior to 49% EASI75 achieved by dupilumab.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Eli Lilly and Company (LLY)			
1185	**Izokibep** **NCTID: NCT05623345** **Phase: Phase 2 Phase 3** **Class: Best-In-Class** **Modality: small protein scaffold-based biologic** **MoA: IL-17A Inhibitior** **Area: Musculoskeletal Diseases** **Indication: Psoriatic Arthritis** **Human Patients: 351** **Sponsor: Acelyrin (SLRN)**	Date: 20 Nov 2023 Quarter: Q1'24 Batch 2 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially insufficient clinical benefit with non-superior-to-bimekizumab efficacy and inferior-to-bimekizumab toxicity)	Readout: 11 Mar 2024 **Lead Time: 112 days in advance** Interpretation: 28% placebo-controlled ACR50 response at wk 16 with 2.5% discontinuation rate; which is infereior to 36% placebo-controlled ACR50 response at wk 16 and 0.4% discontinuation rate; achieved by bimekizumab (DOI-10.1016/S0140-6736(22)02303-0).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
999	**AOC 1001** **NCTID: NCT05027269** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small interfering RNA (siRNA) antisense oligonucleotide** **MoA: anti-DMPK siRNA** **Area: Musculoskeletal Diseases** **Indication: Myotonic Dystrophy Type 1 (DM1)** **Human Patients: 38** **Sponsor: Avidity Biosciences (RNA)**	Date: 22 Apr 2023 Quarter: Q2'23 Batch 16 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commerciall insufficient clinical benefit)	Readout: 4 Mar 2024 **Lead Time: 317 days in advance** Interpretation: no change in toxicity or efficacy in OLE	Correct Prediction Conclusion: statistical insignificant and commercially insufficient Classification: **True Negative (TN)**
929	**PL9643 Vehicle Opthalmic Solution Opthalmic Solution** **NCTID: NCT05201170** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: MC1R/MC5R agonist** **Area: Eye Diseases** **Indication: Dry Eye** **Human Patients: 240** **Sponsor: Palatin Technologies (PTN)**	Date: 7 Mar 2023 Quarter: - Batch - Technical: FAILURE Commercial: FAILURE	Readout: 28 Feb 2024 **Lead Time: 358 days in advance** Interpretation: key primary and secondary endpoints not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1336	**ARS-1** **NCTID: NCT05496465** **Phase: Phase 2** **Class: Best-In-Class** **Modality: medical device** **MoA: epinephrine spray** **Area: Skin and Connective Tissue Diseases** **Indication: Urticaria** **Human Patients: 24** **Sponsor: ARS Pharmaceuticals (SPRY)**	Date: 20 Nov 2023 Quarter: 2H'23 Batch 30 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 26 Feb 2024 **Lead Time: 98 days in advance** Interpretation: primary endpoint met with p<0.05 that's not comparable with CDX0159 that achieved 40.6% placebo-adjusted CR.	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: **True Negative (TN)**
1466	**Gepotidacin Ceftriaxone Azithromycin** **NCTID: NCT04010539** **Phase: Phase 3** **Class: First-In-Class** **Modality: small molecule** **MoA: oral inhibitor of bacterial DNA gyrase and topoisomerase IV** **Area: Infections** **Indication: Urinary Tract Infections** **Human Patients: 628**	Date: 15 Feb 2024 Quarter: Q2'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 26 Feb 2024 **Lead Time: 11 days in advance** Interpretation: primary endpoint of non-inferiority to SoC met.	Correct Prediction Conclusion: statistically significant and commercially sufficient (non-inferiority is sufficient given the high efficacy of antiboitics and high rate of resistance). Classification: **True Positive (TP)**

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: GSK (GSK)			
1412	**TP-05** **NCTID: NCT05387083** **Phase: Phase 2** **Class: First-In-Class** **Modality: small molecule** **MoA: anti-GABACl inhibitor** **Area: Infections** **Indication: Lyme Disease** **Human Patients: 30** **Sponsor: Tarsus Pharmaceuticals (TARS)**	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 22 Feb 2024 **Lead Time: 38 days in advance** Interpretation: primary endpoint and key secondary endpoint met 97% vs 5% tick mortality p<0.0001.	Correct Prediction Conclusion: statistically significant and commercially sufficient (theoretical efficacy upper limit) Classification: **True Positive (TP)**
1181	**ADVM-022** **NCTID: NCT05536973** **Phase: Phase 2** **Class: First-In-Class** **Modality: gene therapy** **MoA: AAV aflibercept gene therapy** **Area: Eye Diseases** **Indication: Neovascular Age-related Macular Degeneration** **Human Patients: 69** **Sponsor: Adverum Biotechnologies (ADVM)**	Date: 18 Jul 2023 Quarter: 2H'23 Batch 7 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to aflibercept)	Readout: 8 Feb 2024 **Lead Time: 205 days in advance** Interpretation: -1.7 BCVA 26 weeks vs +4 BCVA for 24 weeks achieved by ranibizumab; negative dose-response relationship	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1004	**4D-150 IVT Aflibercept IVT** **NCTID: NCT05197270** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: gene therapy** **MoA: AAV aflibercept and VEGFC RNAi gene therapy** **Area: Eye Diseases** **Indication: Neovascular (Wet) Age-Related Macular Degeneration** **Human Patients: 150** **Sponsor: 4D Molecular Therapeutics (FDMT)**	Date: 3 Dec 2023 Quarter: Q1'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to aflibercept)	Readout: 3 Feb 2024 **Lead Time: 62 days in advance** Interpretation: #ERROR!	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
1161	**RGX-314 Ranibizumab Local steroid Topical steroid** **NCTID: NCT04514653** **Phase: Phase 2** **Class: First-In-Class** **Modality: gene therapy** **MoA: AAV anti-VEGF gene therapy** **Area: Eye Diseases** **Indication: Neovascular Age-Related Macular Degeneration (nAMD)** **Human Patients: 115** **Sponsor: AbbVie / REGENXBIO (ABBV/RGNX)**	Date: 9 Jul 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit inferior to ranibizumab) Commercial: FAILURE (commercially insufficient clinical benefit inferior to ranibizumab)	Readout: 16 Jan 2024 **Lead Time: 191 days in advance** Interpretation: -1 to -2.8 BCVA 6 months vs +4 for ranibizumab.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**
1089	**Lirentelimab (AK002)** **NCTID: NCT05155085** **Phase: Phase 2** **Class: First-In-Class** **Modality: monoclonal antibody (mAb)** **MoA: SIGLEC8 mAb inhibitor** **Area: Skin and Connective**	Date: 6 Jun 2023 Quarter: 2H'23 Batch 3 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit for refractory patients superior	Readout: 16 Jan 2024 **Lead Time: 224 days in advance** Interpretation: primary endpoint not met.	Missed Prediction Note: due to suboptimal drug MoA modelling that has been permanently corrected. Conclusion: statistically insignificant commercially insufficient

Validated Trial Evidence: Filtered Registry (80 of 604 trials)

Filtered view: **Infections** **Eye/Skin/Muscul**

#	Clinical Trial	Certified Prediction	Validation	Result
	Tissue Diseases **Indication: Atopic Dermatitis** **Human Patients: 131** **Sponsor: Allakos (ALLK)**	to omalizumab)		Classification: **False Positive (FP)**
770	**ATI-1777** **NCTID: NCT05432596** **Phase: Phase 2** **Class: Best-In-Class** **Modality: small molecule** **MoA: JAK1/JAK3 inhibitor** **Area: Skin and Connective Tissue Diseases** **Indication: Atopic Dermatitis** **Human Patients: 250** **Sponsor: Aclaris Therapeutics (ACRS)**	Date: 7 Jan 2024 Quarter: Q1'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit due to crowded market)	Readout: 10 Jan 2024 **Lead Time: 3 days in advance** Interpretation: ATI1777 achieved 70% EASI with 11% delta vs dupilumab that achieved 72-80% EASI with 40% delta.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: **True Negative (TN)**
1254	**DYNE-101** **NCTID: NCT05481879** **Phase: Phase 1 Phase 2** **Class: First-In-Class** **Modality: small interfering RNA (siRNA) antisense oligonucleotide** **MoA: anti-DMPK siRNA** **Area: Musculoskeletal Diseases** **Indication: Myotonic Dystrophy Type 1** **Human Patients: 72** **Sponsor: Dyne Therapeutics (DYN)**	Date: 21 Nov 2023 Quarter: Q1'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in 10MWR)	Readout: 3 Jan 2024 **Lead Time: 43 days in advance** Interpretation: 40% DMPK knowddown and 3.8 second benefit in myotonia at 6 months; no report of key 10MWR functional endpoints.	Correct Prediction Note: correct technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD Classification: **True Positive (TP)**
963	**Efgartigimod** **NCTID: NCT04598451** **Phase: Phase 3** **Class: First-In-Class** **Modality: antibody fragment biologic** **MoA: anti-FcRn antibody fragment** **Area: Skin and Connective Tissue Diseases** **Indication: Pemphigus** **Human Patients: 222** **Sponsor: argenx (ARGX)**	Date: 4 Jul 2023 Quarter: 2H'23 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 20 Dec 2023 **Lead Time: 169 days in advance** Interpretation: primary or secondary endpoints not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: **True Negative (TN)**

Appendix: Statistical Methodology & Glossary

KPI FORMULAS

Accuracy
`(TP + TN) / (TP + TN + FP + FN)`

Precision (PPV)
`TP / (TP + FP)`

NPV
`TN / (TN + FN)`

F1-Score
`2 × TP / (2 × TP + FP + FN)`

DOR
`(TP × TN) / (FP × FN)`

Sensitivity
`TP / (TP + FN)`

Specificity
`TN / (TN + FP)`

GLOSSARY

Ex-Ante / Prospective	Prediction issued before outcome is known; timestamped proof
TP	True Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, confirmed by clinical readout
TN	True Negative — predicted non-blockbuster drug-indicatpion pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, confirmed by clinical readout
FP	False Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, contradicted by clinical readout
FN	False Negative — predicted non-blockbuster drug-indicatpion pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, contradicted by clinical readout
FIC	First-In-Class — novel mechanism of action and indication pair, no approved precedent
BIC	Best-In-Class — improved agent within an established class
DOR	Diagnostic Odds Ratio — measures discriminative power
MoA	Mechanism of Action — how a drug exerts its therapeutic effect
SoC	Standard of Care — current best available treatment
NCTID	ClinicalTrials.gov trial identifier (e.g., NCT12345678)

DATA PROVENANCE

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

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

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