TROY TECHNICAL

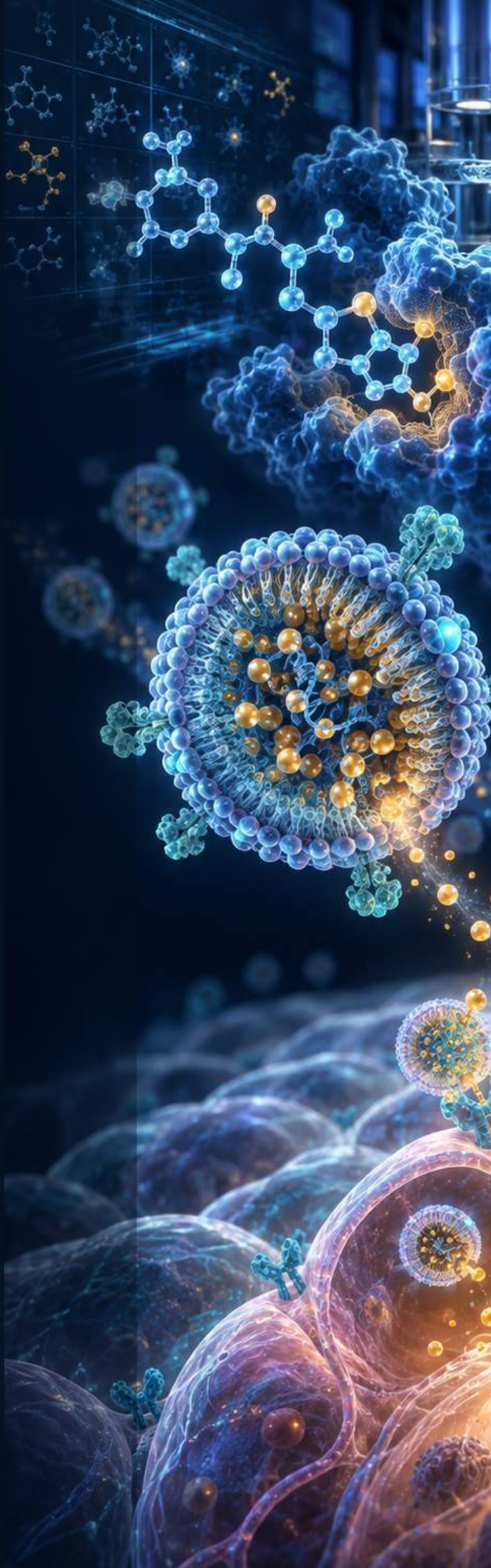
DRUG DISCOVERY & DDS
WEEKLY REPORT

November 14 - November 20, 2026 | Issue 2026-W46

Target validation, translational evidence, delivery and development economics

16	10
ANALYZED ARTICLES	PRIORITY THEMES

Issued 2026-11-20 | English edition | fixed approved cover artwork



Drug Discovery & DDS: the boundary moved from isolated claims to qualification evidence

16 English articles were reviewed independently from the Japanese edition. Ten themes are retained for management decisions.

SIGNAL 01 | TARGET & MOLECULE

Obinutuzumab: FDA Approval for Primary Membranous Nephropathy

The FDA has approved obinutuzumab (Gazyva) as the first on-label therapy for adults with primary membranous nephropathy (PMN) at risk of disease progression.

SIGNAL 02 | DELIVERY DESIGN

Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results

The FDA has approved cemdisiran (Livsayis), a complement C5-directed siRNA, for adults with AChR-antibody-positive generalized myasthenia gravis (gMG).

SIGNAL 03 | PRECLINICAL PROOF

HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA

HUTCHMED has received simultaneous approval from China's NMPA for SYVIK (sovleplenib), the first novel oral Syk inhibitor approved in China.

SIGNAL 04 | CLINICAL DEVELOPMENT

Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU

AstraZeneca's Baxfendy (baxdrostat) has received a positive CHMP opinion for treating adults in the EU with arterial hypertension insufficiently controlled by at least two medicines.

DECISION

Focus this week's management attention on target validation, translational evidence, delivery and development economics. Move only when the linked evidence can be reproduced under your own operating conditions.

THREE MANAGEMENT MOVES

1. Buyers: separate platform promise from program-level evidence, safety and clinical differentiation.
2. Suppliers: tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.
3. Executives: track reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EVIDENCE DISCIPLINE

FACT states what the collected English source reports. BUSINESS READ and ACTION are editorial interpretations. UNKNOWN lists information that the source file does not establish. A linked article is not treated as independent confirmation of every claim.

Numbers and evidence anchors that require conditions

36%
A05

SOURCE-BOUND CONDITION
In a phase 3 trial, 36% of patients achieved complete proteinuria remission compared to 6% receiving tacrolimus.

68G
A06

SOURCE-BOUND CONDITION
Clinical data shows the agent detects significantly more lesions than 68Ga-PSMA-11, with 78% patient-level positivity compared to 36%.

41%
A14

SOURCE-BOUND CONDITION
The Phase 3 REGAL trial of the immunotherapeutic cancer vaccine galinpepimut-S (GPS) demonstrated a 41% reduction in the risk of death compared to the best available treatment in AML patients.

49%
A04

SOURCE-BOUND CONDITION
Data from the ALKOVE-1 trial showed an overall response rate (ORR) of 49% in patients previously treated with alectinib, providing a new option for advanced NSCLC populations.

87%
A07

SOURCE-BOUND CONDITION
Phase 2 SCOPE data showed a 24-month overall survival rate of 87% for the iSCIB1+ cohort, supporting a global phase 3 trial scheduled to enroll its first patient in December 2026.

HOW TO USE THESE NUMBERS
Each value is shown with the condition stated in the collected English article. Do not compare values across different test methods, device sizes, operating temperatures or commercial stages without normalizing those conditions.

Where the value chain moved

Each stage combines one leading theme and one supporting theme. The report treats handoffs as evidence transfers, not decorative arrows.

1

Target & molecule

P01/P06

The FDA has approved obinutuzumab (Gazyva) as the first on-label therapy for adults with primary membranous nephropathy (PMN).

2

Delivery design

P02/P07

The FDA has approved cemdisiran (Livsayis), a complement C5-directed siRNA, for adults with AChR-antibody-positive.

3

Preclinical proof

P03/P08

HUTCHMED has received simultaneous approval from China's NMPA for SYVIK (sovleplenib), the first novel oral Syk inhibitor.

4

Clinical development

P04/P09

AstraZeneca's Baxfendy (baxdrostat) has received a positive CHMP opinion for treating adults in the EU with arterial.

5

Access & portfolio

P05/P10

The FDA has granted breakthrough therapy designation to 64Cu-SAR-bisPSMA for PSMA PET imaging in men with suspected.

EVIDENCE REQUIRED AT EACH HANDOFF

Target & molecule to Delivery design	Transfer test conditions, acceptance criteria, failure data, owner and decision date. Recheck reproducibility, biodistribution, toxicity, CMC, trial design and financing.
Delivery design to Preclinical proof	Transfer test conditions, acceptance criteria, failure data, owner and decision date. Recheck reproducibility, biodistribution, toxicity, CMC, trial design and financing.
Preclinical proof to Clinical development	Transfer test conditions, acceptance criteria, failure data, owner and decision date. Recheck reproducibility, biodistribution, toxicity, CMC, trial design and financing.
Clinical development to Access & portfolio	Transfer test conditions, acceptance criteria, failure data, owner and decision date. Recheck reproducibility, biodistribution, toxicity, CMC, trial design and financing.

COMMON CONTROL POINT

No theme moves to a commercial commitment until a named owner has reproduced the relevant evidence and documented reproducibility, biodistribution, toxicity, CMC, trial design and financing.

Priority map: maturity and next decision locus



P01	Obinutuzumab: FDA Approval for Primary Membranous Nephropathy Business / rules | cue: FDA
P02	Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results Business / rules | cue: FDA
P03	HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA Tech / process | cue: no system/business cue
P04	Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU Tech / process | cue: no system/business cue
P05	64Cu-SAR-bisPSMA: FDA Breakthrough Designation and Clinical Data Business / rules | cue: FDA
P06	SELLAS Life Sciences: GPS Phase 3 REGAL trial OS results for AML System / adoption | cue: Phase 3
P07	Neladalkib: FDA Accelerated Approval and ALKOVE-1 Trial Data Business / rules | cue: FDA
P08	iSCIB1+: Scancell's RMAT designation and Phase 3 timeline System / adoption | cue: Phase 3
P09	Corxel US CX11: Phase 2 Weight Loss Results and Safety Profile System / adoption | cue: Phase 2
P10	Priavoid PRI-002: Phase 2 Alzheimer's Data and CTAD 2026 Results System / adoption | cue: Phase 2

REPRODUCIBLE POSITIONING RULE

Horizontal position uses five discrete stages: Research, Prototype, Joint evaluation, Product adoption and Scale. The vertical bands classify the next decision locus: Tech / process, System / adoption, or Business / rules (including supply systems). Article-title cues take precedence; the overview is used only when the title is silent. These are categories, not impact ranks. Bubble diameter reflects the editorial score.

FACT is source-bound. BUSINESS READ, ACTION and UNKNOWN are explicit editorial layers.

P01 Obinutuzumab: FDA Approval for Primary Membranous Nephropathy

A05 | Target & molecule | Scale-up

2026-11-18

FACT

The FDA has approved obinutuzumab (Gazyva) as the first on-label therapy for adults with primary membranous nephropathy (PMN) at risk of disease progression. In a phase 3 trial, 36% of patients achieved complete proteinuria remission compared to 6% receiving tacrolimus. This provides a targeted treatment for a rare autoimmune disease where 30% of untreated cases progress to kidney failure within 10 years.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P01.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 21/25 | MATURITY 5/5 | DECISION LOCUS: BUSINESS / RULES

P02 Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results

A03 | Delivery design | Scale-up

2026-11-18

FACT

The FDA has approved cemdisiran (Livsayis), a complement C5-directed siRNA, for adults with AChR-antibody-positive generalized myasthenia gravis (gMG). The therapy enables quarterly subcutaneous dosing by suppressing hepatic C5 production, offering a less frequent administration schedule than existing complement-targeted options.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P02.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 21/25 | MATURITY 5/5 | DECISION LOCUS: BUSINESS / RULES

FACT is source-bound. BUSINESS READ, ACTION and UNKNOWN are explicit editorial layers.

P03 HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA

A12 | Preclinical proof | Scale-up

2026-11-19

FACT

HUTCHMED has received simultaneous approval from China's NMPA for SYVIK (sovleplenib), the first novel oral Syk inhibitor approved in China. The drug is indicated for adult patients with primary immune thrombocytopenia (ITP) and warm antibody autoimmune hemolytic anemia (wAIHA) who showed insufficient response to prior therapies.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P03.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 5/5 | DECISION LOCUS: TECH / PROCESS

P04 Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU

A09 | Clinical development | Joint evaluation

2026-11-16

FACT

AstraZeneca's Baxfendy (baxdrostat) has received a positive CHMP opinion for treating adults in the EU with arterial hypertension insufficiently controlled by at least two medicines. Phase III trials demonstrated significant reductions in systolic blood pressure, positioning the drug to become the first and only aldosterone synthase inhibitor in the EU.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P04.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: TECH / PROCESS

FACT is source-bound. BUSINESS READ, ACTION and UNKNOWN are explicit editorial layers.

P05 64Cu-SAR-bisPSMA: FDA Breakthrough Designation and Clinical Data

A06 | Access & portfolio | Research

2026-11-17

FACT

The FDA has granted breakthrough therapy designation to 64Cu-SAR-bisPSMA for PSMA PET imaging in men with suspected biochemical recurrence of prostate cancer. Clinical data shows the agent detects significantly more lesions than 68Ga-PSMA-11, with 78% patient-level positivity compared to 36%. This designation accelerates the development of a bivalent imaging agent capable of extended imaging windows due to the 12.7-hour half-life of copper-64.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P05.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 1/5 | DECISION LOCUS: BUSINESS / RULES

P06 SELLAS Life Sciences: GPS Phase 3 REGAL trial OS results for AML

A14 | Target & molecule | Joint evaluation

2026-11-17

FACT

The Phase 3 REGAL trial of the immunotherapeutic cancer vaccine galinpepimut-S (GPS) demonstrated a 41% reduction in the risk of death compared to the best available treatment in AML patients. Median overall survival increased to 24.0 months from 14.7 months, providing a potential new maintenance therapy for high-risk patients ineligible for stem cell transplantation.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P06.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: SYSTEM / ADOPTION

FACT is source-bound. BUSINESS READ, ACTION and UNKNOWN are explicit editorial layers.

P07 Neladalkib: FDA Accelerated Approval and ALKOVE-1 Trial Data

A04 | Delivery design | Joint evaluation

2026-11-17

FACT

The FDA has granted accelerated approval to neladalkib (Nelkarmi) for patients with ALK-positive non-small cell lung cancer (NSCLC) previously treated with tyrosine kinase inhibitors (TKIs). Data from the ALKOVE-1 trial showed an overall response rate (ORR) of 49% in patients previously treated with alectinib, providing a new option for advanced NSCLC populations.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P07.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: BUSINESS / RULES

P08 iSCIB1+: Scancell's RMAT designation and Phase 3 timeline

A07 | Preclinical proof | Joint evaluation

2026-11-19

FACT

The FDA has granted Regenerative Medicine Advanced Therapy (RMAT) designation to iSCIB1+, a DNA-based immunotherapy for advanced melanoma. Phase 2 SCOPE data showed a 24-month overall survival rate of 87% for the iSCIB1+ cohort, supporting a global phase 3 trial scheduled to enroll its first patient in December 2026.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P08.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: SYSTEM / ADOPTION

FACT is source-bound. BUSINESS READ, ACTION and UNKNOWN are explicit editorial layers.

P09 Corxel US CX11: Phase 2 Weight Loss Results and Safety Profile

A11 | Clinical development | Joint evaluation

2026-11-16

FACT

Corxel US reported that its oral GLP-1 receptor agonist CX11 achieved mean weight loss of 9.3% to 11.5% over 36 weeks in adults with overweight and obesity. The trial showed no weight plateau and a safety profile consistent with the GLP-1 RA class, providing a foundation for upcoming global Phase 3 studies.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P09.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: SYSTEM / ADOPTION

P10 Priavoid PRI-002: Phase 2 Alzheimer's Data and CTAD 2026 Results

A13 | Access & portfolio | Joint evaluation

2026-11-17

FACT

Priavoid's Phase 2 trial of the oral all-D-peptide PRI-002 met its primary safety endpoint but failed to meet its primary efficacy endpoint (CDR-SB) at Week 48. However, the study showed a 35.9% slowing of cognitive decline on ADAS-Cog at Week 72 in the per protocol population (p=0.022), suggesting potential as a disease-modifying treatment.

WHY IT MATTERS

The decision relevance is target validation, translational evidence, delivery and development economics. The signal should be tested at the application and operating-system level, not accepted from a headline alone.

BUSINESS READ

For operating companies, compare the reported change with current qualification, sourcing and product-roadmap assumptions. For suppliers, tie formulation, carriers and analytics to exposure, manufacturability and regulatory control.

ACTION

Within 30 days, separate platform promise from program-level evidence, safety and clinical differentiation; record the evidence and owner against P10.

UNKNOWN

Still unproven or incompletely stated: reproducibility, biodistribution, toxicity, CMC, trial design and financing.

EDITORIAL SCORE 20/25 | MATURITY 3/5 | DECISION LOCUS: SYSTEM / ADOPTION

Playbook and 0-5 year roadmap

STAKEHOLDER	NOW | 0-30 DAYS	NEXT | 1-12 MONTHS	LATER | 1-5 YEARS
Operating companies	separate platform promise from program-level evidence, safety and clinical differentiation	Run production-like qualification with explicit acceptance and stop criteria.	Build a portfolio and architecture that can absorb technology and supplier changes.
Materials, equipment and technology suppliers	tie formulation, carriers and analytics to exposure, manufacturability and regulatory control	Create shared reliability, process-window and failure-analysis data with customers.	Standardize interfaces, traceability, lifecycle support and recovery services.
Trading, investment and legal teams	Map reproducibility, biodistribution, toxicity, CMC, trial design and financing.	Contract for capacity, quality, change notice, liability, alternatives and exit.	Diversify regional, technical and customer concentration risk.

ROADMAP

NOW | 0-30 DAYS
Evidence ledger
Owner: Strategy + quality
Deliverable: claim, source, condition, owner

NOW | 0-30 DAYS
Risk screen
Owner: Procurement + legal
Deliverable: unknowns, alternatives, stop

NEXT | 1-12 MONTHS
Joint qualification
Owner: R&D + supplier
Deliverable: process window and failure data

NEXT | 1-12 MONTHS
Commercial gate
Owner: Business + finance
Deliverable: unit economics and capacity

LATER | 1-5 YEARS
Platform strategy
Owner: Executive team
Deliverable: portfolio and interface roadmap

LATER | 1-5 YEARS
Service layer
Owner: Operations + channel
Deliverable: monitoring, maintenance and recovery

GO / NO-GO GATES

GATE	OWNER	REQUIRED EVIDENCE	NO-GO CONDITION
G1 Evidence	**Quality**	Source, test conditions and reproducibility	No traceable evidence
G2 Integration	**R&D**	Interface, process window and failure analysis	Cannot meet system conditions
G3 Commercial	**Business**	Capacity, total cost, contract and alternatives	Economics or supply cannot be supported
G4 Lifecycle	**Operations**	Monitoring, maintenance, change notice and exit	No accountable operating plan

ANALYZED ARTICLES | ITEMS 01-08

Every title and URL is displayed in full. URLs wrap without shortening and remain clickable. A verified-reference label means the translated HTML did not retain its original source URL.

ID	FULL ARTICLE TITLE	FULL SOURCE / VERIFIED REFERENCE URL - CLICKABLE
A01	Tz-SS2009: HER2-targeted molecular glue degrader for CCNK	https://doi.org/10.64898/2026.11.12.760175
A02	ADC Toxicity Atlas: Payload and Target-Informed FAERS Analysis	https://doi.org/10.21203/rs.3.rs-11179015/v1
A03	Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results	https://www.neurologylive.com/view/fda-approves-cemdisiran-as-new-treatment-generalized-myasthenia-gravis
A04	Neladalkib: FDA Accelerated Approval and ALKOVE-1 Trial Data	https://www.cancernetwork.com/view/fda-approves-neladalkib-in-advanced-alk-non-small-cell-lung-cancer
A05	Obinutuzumab: FDA Approval for Primary Membranous Nephropathy	https://www.ajmc.com/view/fda-approves-obinutuzumab-as-first-therapy-for-membranous-nephropathy
A06	64Cu-SAR-bisPSMA: FDA Breakthrough Designation and Clinical Data	https://www.cancernetwork.com/view/64cu-sar-bispsma-earns-fda-breakthrough-designation-in-recurrent-prostate-cancer
A07	iSCIB1+: Scancell's RMAT designation and Phase 3 timeline	https://www.targetedonc.com/view/fda-grants-rmat-designation-iscib1-advanced-melanoma
A08	Belzutifan plus Lenvatinib: CHMP positive opinion for ccRCC	https://www.cancernetwork.com/view/belzutifan-plus-lenvatinib-earns-positive-chmp-opinion-in-advanced-ccrcc

ANALYZED ARTICLES | ITEMS 09-16

Every title and URL is displayed in full. URLs wrap without shortening and remain clickable. A verified-reference label means the translated HTML did not retain its original source URL.

ID	FULL ARTICLE TITLE	FULL SOURCE / VERIFIED REFERENCE URL - CLICKABLE
A09	Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU	https://news.europawire.eu/astrazenecas-baxfendy-receives-positive-chmp-opinion-for-uncontrolled-hypertension-in-the-eu/eu-press-release/2026/11/16/13/52/05/188047/
A10	BHV-1530: Biohaven's FGFR3-Directed ADC Phase 1 Clinical Data	https://finance.yahoo.com/healthcare/articles/biohavens-novel-fgfr3-directed-adc-123000296.html
A11	Corxel US CX11: Phase 2 Weight Loss Results and Safety Profile	https://finance.yahoo.com/healthcare/articles/corxel-us-presents-full-phase-133400036.html
A12	HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA	https://markets.businessinsider.com/news/stocks/hutchmed-announces-china-nmpa-approval-of-syvik-sovleplenib-for-the-treatment-of-primary-immune-thrombocytopenia-and-warm-antibody-autoimmune-hemolytic-anemia-1036783084
A13	Priavoid PRI-002: Phase 2 Alzheimer's Data and CTAD 2026 Results	https://markets.businessinsider.com/news/stocks/priavoid-announces-topline-phase-2-data-for-oral-all-d-peptide-pri-002-in-alzheimer-s-disease-at-ctad-2026-1036774435
A14	SELLAS Life Sciences: GPS Phase 3 REGAL trial OS results for AML	https://www.theglobeandmail.com/investing/markets/markets-news/GlobeNewswire/8872029/sellas-life-sciences-announces-positive-pivotal-phase-3-regal-trial-data-showing-immunotherapeutic-cancer-vaccine-galinpepimut-s-gps-demonstrated-a-statistically-significant-and-clinically-meaningful-improvement-in-overall-survival-in-patients/
A15	Leqembi: 3-Year Real-World Data on Alzheimer's Progression and Safety	https://www.prnewswire.com/news-releases/new-three-year-real-world-data-on-leqembi-presented-at-ctad-2026-302944141.html
A16	Acoramidis: ATTR-CM outcomes vs tafamidis and placebo in 2026	https://markets.businessinsider.com/news/stocks/acoramidis-was-associated-with-lower-risk-of-worsening-heart-failure-versus-tafamidis-in-real-world-study-and-reduced-heart-failure-events-within-one-month-in-attribute-cm-1036773552

DrugDiscovery_DDS — Selected Articles

Date: 2026-11-21

Articles: 16

Table of Contents

#01 Tz-SS2009: HER2-targeted molecular glue degrader for CCNK

#02 ADC Toxicity Atlas: Payload and Target-Informed FAERS Analysis

#03 Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results

#04 Neladalkib: FDA Accelerated Approval and ALKOVE-1 Trial Data

#05 Obinutuzumab: FDA Approval for Primary Membranous Nephropathy

#06 64Cu-SAR-bisPSMA: FDA Breakthrough Designation and Clinical Data

#07 iSCIB1+: Scancell's RMAT designation and Phase 3 timeline

#08 Belzutifan plus Lenvatinib: CHMP positive opinion for ccRCC

#09 Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU

#10 BHV-1530: Biohaven's FGFR3-Directed ADC Phase 1 Clinical Data

#11 Corxel US CX11: Phase 2 Weight Loss Results and Safety Profile

#12 HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA

#13 Priavoid PRI-002: Phase 2 Alzheimer's Data and CTAD 2026 Results

#14 SELLAS Life Sciences: GPS Phase 3 REGAL trial OS results for AML

#15 Leqembi: 3-Year Real-World Data on Alzheimer's Progression and Safety

#16 Acoramidis: ATTR-CM outcomes vs tafamidis and placebo in 2026

#01 Tz-SS2009: HER2-targeted molecular glue degrader for CCNK

Published November 13, 2026 bioRxiv



OVERVIEW

Researchers have developed Tz-SS2009, a degrader-antibody conjugate that targets the HER2 receptor to induce selective degradation of cyclin K (CCNK). This approach enhances antiproliferative effects in HER2-positive breast cancer cells while reducing the potential for broad systemic toxicity.

IN DEPTH

Key Findings

The study demonstrates that antibody-mediated delivery can successfully redistribute the activity of a potent molecular glue degrader toward antigen-positive cells. The resulting conjugate, Tz-SS2009, preferentially internalizes in HER2-positive cells, leading to enhanced CCNK degradation and stronger antiproliferative effects compared to HER2-negative cells or an isotype-matched non-targeting conjugate.

Technical Details

The researchers focused on the CR8/DS18 purine series to develop SAS1001, a CCNK molecular glue degrader. Because molecular glues lack the modular architecture of PROTACs, the team identified a solvent-exposed piperazine position for linker attachment to ensure that conjugation would not compromise activity. SAS1001 was found to induce potent, ubiquitin-proteasome system-dependent degradation of CCNK and inhibit proliferation across various breast cancer cell lines.

To achieve cellular selectivity, SAS1001 was conjugated to the antibody trastuzumab (Tz), creating the Tz-SS2009 conjugate. Whole proteome analysis confirmed the depletion of CCNK and identified downstream changes consistent with the known roles of the CDK12/CCNK complex in transcriptional regulation.

Background & Context

Cyclin-dependent kinase 12 (CDK12) is a critical target for therapy due to its role in DNA damage response and transcriptional regulation; it is frequently co-amplified with ERBB2 (HER2) in breast cancer. CDK12 requires its partner, cyclin K (CCNK), to form an active complex. While pharmacological degradation of CCNK is a promising strategy to disrupt CDK12-dependent programs, the essential functions and broad expression of the CDK12/CCNK complex often limit the therapeutic window for highly potent molecular glue degraders.

Significance & Outlook

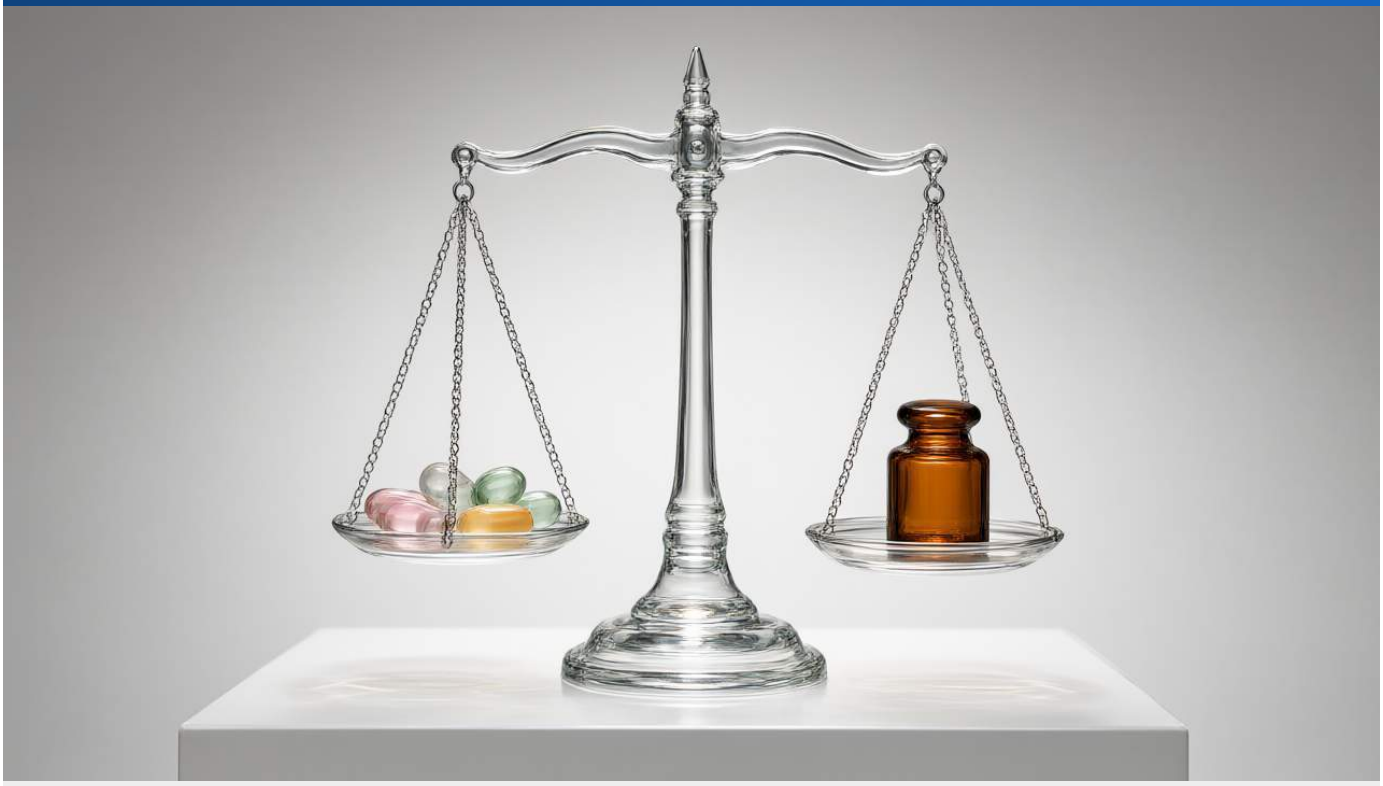
This work extends the application of antibody-directed degradation beyond the CRBN-based glues that have previously dominated the field. By using structural characterization to identify a linker attachment point that preserves activity when delivered via a full-length IgG, the study provides a framework for improving the selectivity and therapeutic index of molecular glue degraders.

Source: https://doi.org/10.64898/2026.11.12.760175

Collected: November 21, 2026 | Automated Research System (AI)

#02 ADC Toxicity Atlas: Payload and Target-Informed FAERS Analysis

Published November 12, 2026 Research Square



OVERVIEW

A disproportionality analysis of the FDA Adverse Event Reporting System (FAERS) identifies distinct toxicity profiles across 13 antibody-drug conjugates (ADCs). The study reveals that toxicity is driven more by payload class than by target antigen, with topoisomerase-I inhibitors showing the highest pulmonary risk.

IN DEPTH

Key Findings

The analysis of 62,079 reports across 13 ADCs identified 71 signals of disproportionate reporting. Interstitial lung disease (ILD)/pneumonitis was the most widespread toxicity cluster, appearing in 12 ADCs. Other prevalent signals included neutropenia/hematologic toxicity and thrombocytopenia/bleeding (11 signals each), followed by hepatotoxicity (nine), gastrointestinal toxicity (eight), and neuropathy, ocular toxicity, and skin toxicity (six each).

Technical Details

Toxicity profiles varied significantly by agent and payload:

- **HER2-directed ADCs:** Trastuzumab deruxtecan showed a strong pulmonary pattern (ILD/pneumonitis in 13.94% of reports; ROR 22.61), whereas T-DM1 was characterized by hepatotoxicity (ROR 8.20) and thrombocytopenia/bleeding (ROR 7.05).
- **Ocular Toxicity:** This was the most concentrated phenotype, dominated by belantamab mafodotin (39.78% of reports; ROR 36.77) and mirvetuximab soravtansine (18.09%; ROR 12.27).
- **Hematologic Toxicity:** High RORs were observed for gemtuzumab ozogamicin (ROR 21.78), sacituzumab govitecan (ROR 13.17), and polatuzumab vedotin (ROR 12.15).
- **Multidimensional Profiles:** Enfortumab vedotin exhibited a broad profile including skin toxicity (28.89%; ROR 7.47), neuropathy (15.10%; ROR 9.79), and hyperglycemia (6.25%; ROR 4.74).

Payload-Level Architecture

Aggregation by payload class revealed convergent patterns. Topoisomerase-I inhibitor ADCs showed the greatest pulmonary enrichment (ILD/pneumonitis ROR 15.83). Vedotin/MMAE ADCs displayed a broader pattern including neutropenia/hematologic toxicity (ROR 9.61) and neuropathy (ROR 6.32). Calicheamicin-containing ADCs were characterized by neutropenia/hematologic toxicity (ROR 15.31) and hepatotoxicity (ROR 8.02).

Significance and Outlook

The data demonstrates that shared target antigens do not result in interchangeable reporting profiles. Instead, the toxicity phenotype is heavily influenced by the payload, providing a map for predicting and managing adverse events based on the ADC's structural components.

Source: https://doi.org/10.21203/rs.3.rs-11179015/v1

Collected: November 21, 2026 | Automated Research System (AI)

#03 Cemdisiran (Livsayis): FDA Approval and NIMBLE Trial Results

Published November 18, 2026 NeurologyLive USA



OVERVIEW

The FDA has approved cemdisiran (Livsayis), a complement C5-directed siRNA, for adults with AChR-antibody-positive generalized myasthenia gravis (gMG). The therapy enables quarterly subcutaneous dosing by suppressing hepatic C5 production, offering a less frequent administration schedule than existing complement-targeted options.

IN DEPTH

Key Findings

Cemdisiran (Livsayis) demonstrated rapid and deep disease control in the Phase 3 NIMBLE trial. The primary endpoint, change in Myasthenia Gravis Activities of Daily Living (MG-ADL) score at week 24, showed an improvement of 4.5 points for cemdisiran versus 2.2 points for placebo (placebo-adjusted difference of 2.3 points; P =.0005). Furthermore, 76.6% of cemdisiran patients achieved a clinically meaningful improvement of 3 points or more, compared to 44.1% in the placebo group (P <.001).

Technical Details

Unlike C5-binding agents that target circulating proteins, cemdisiran is a small interfering RNA (siRNA) that degrades the messenger RNA encoding complement component 5 (C5). This mechanism reduces hepatic production of C5 before it enters circulation, limiting terminal complement activation. The drug is administered via subcutaneous injection once every 3 months.

Secondary endpoints from the NIMBLE trial include:

- Quantitative Myasthenia Gravis (QMG) score improvement: 4.2 points for cemdisiran vs 1.5 points for placebo (P =.0015).
- QMG improvement of 5 points or more: achieved by 48.4% of cemdisiran patients vs 19.0% of placebo patients (P <.001).
- Onset of improvement: observed as early as 2 weeks after the first dose.

Background & Context

The NIMBLE trial evaluated four arms: cemdisiran monotherapy, cemdisiran plus pozelimab, pozelimab monotherapy, and placebo. Results indicated that adding the C5 inhibitor pozelimab did not enhance efficacy over cemdisiran monotherapy. Regarding safety, treatment-emergent adverse events occurred in 69.2% of cemdisiran patients and 77.1% of placebo patients. Common reactions included injection site reactions, viral infections, and urinary tract infections.

Significance & Outlook

Livsayis is the first approved siRNA therapy for gMG and the fourth complement-targeted option, joining eculizumab, ravulizumab, and gefurulimab. It provides the least frequent dosing schedule in its class. Due to the risk of serious meningococcal infections, the drug is subject to a restricted Risk Evaluation and Mitigation Strategy (REMS) program, requiring vaccination at least 2 weeks before the first dose.

Source: https://www.neurologylive.com/view/fda-approves-cemdisiran-as-new-treatment-generalized-myasthenia-gravis

Collected: November 21, 2026 | Automated Research System (AI)

#04 Neladalkib: FDA Accelerated Approval and ALKOVE-1 Trial Data

Published November 17, 2026 CancerNetwork USA



OVERVIEW

The FDA has granted accelerated approval to neladalkib (Nelkarmi) for patients with ALK-positive non-small cell lung cancer (NSCLC) previously treated with tyrosine kinase inhibitors (TKIs). Data from the ALKOVE-1 trial showed an overall response rate (ORR) of 49% in patients previously treated with alectinib, providing a new option for advanced NSCLC populations.

IN DEPTH

Key Findings

The FDA has granted accelerated approval to neladalkib (Nelkarmi) for the treatment of ALK-positive non-small cell lung cancer (NSCLC) in patients previously managed with tyrosine kinase inhibitors (TKIs). The approval covers two specific indications: patients who received one prior ALK TKI consisting of alectinib (Alecensa), and those who received two or more prior ALK TKIs and platinum-based chemotherapy.

Technical Details

Approval was based on the phase 1/2 ALKOVE-1 trial (NCT05384626). Among patients who received one prior ALK TKI consisting of alectinib (n=67), the overall response rate (ORR) was 49% (95% CI: 37%-62%). Of these responding patients, 76% had a duration of response (DOR) of 6 months or greater, and 52% had a DOR of at least 12 months.

In a broader analysis of patients with advanced ALK-positive NSCLC who received any prior ALK TKI (n=63), the ORR was 31% (95% CI, 26%-37%) with a complete response (CR) rate of 2%. Results varied by prior lorlatinib exposure:

- **Lorlatinib-naive (n=63):** ORR 46% (95% CI, 33%-59%), CR rate 5%, and median progression-free survival (PFS) of 14.5 months.
- **Lorlatinib-experienced (n=190):** ORR 26% (95% CI, 20%-33%), CR rate 2%, and median PFS of 4.6 months.

Intracranial ORR was 63% for the lorlatinib-naive group and 21% for the lorlatinib-experienced group. The recommended dose is 150 mg orally once daily.

Safety and Trial Design

The most common treatment-emergent adverse effects (TEAEs) included alanine aminotransferase increases (47%), aspartate aminotransferase increases (44%), constipation (28%), dysgeusia (23%), and peripheral edema (18%). The safety profile was noted to avoid tropomyosin receptor kinase–related neurotoxicities. The ALKOVE-1 trial involved 253 patients with a median age of 56 years, where 57% were female and 66% had no history of smoking.

Significance and Outlook

Neladalkib demonstrates a clinical profile consistent with its design goals for TKI-pretreated patients. The FDA previously granted priority review to the drug in May 2026, leading to this accelerated approval on November 17, 2026.

Source: https://www.cancernetwork.com/view/fda-approves-neladalkib-in-advanced-alk-non-small-cell-lung-cancer

Collected: November 21, 2026 | Automated Research System (AI)

#05 Obinutuzumab: FDA Approval for Primary Membranous Nephropathy

Published November 18, 2026 AJMC USA



OVERVIEW

The FDA has approved obinutuzumab (Gazyva) as the first on-label therapy for adults with primary membranous nephropathy (PMN) at risk of disease progression. In a phase 3 trial, 36% of patients achieved complete proteinuria remission compared to 6% receiving tacrolimus. This provides a targeted treatment for a rare autoimmune disease where 30% of untreated cases progress to kidney failure within 10 years.

IN DEPTH

Key Findings

Obinutuzumab (Gazyva; Genentech) has become the first drug specifically approved by the FDA to induce remission of proteinuria in adults with primary membranous nephropathy (PMN). The approval is based on the MAJESTY phase 3 trial, which demonstrated that obinutuzumab significantly outperformed tacrolimus in achieving complete proteinuria remission. At week 104, 36% of patients treated with obinutuzumab reached complete remission, compared to only 6% in the tacrolimus group.

Technical Details

The MAJESTY study was an open-label, multicenter, randomized controlled trial involving 142 adults. The primary endpoint was defined as a urine protein-creatinine ratio of no more than 0.3 g/g with a stable estimated glomerular filtration rate (eGFR) at week 104, without the use of rescue therapy or early discontinuation. Results published in the New England Journal of Medicine showed that 26 of 71 patients receiving intravenous obinutuzumab achieved complete remission, versus 4 of 70 patients receiving oral tacrolimus (adjusted difference: 31 percentage points; $P < .001$).

Secondary endpoints also favored obinutuzumab, including overall remission (complete or partial) at week 104 and earlier complete remission at week 76. Safety data indicated that the most common adverse reactions were infusion-related reactions, upper respiratory tract infections, and neutropenia. The drug's label includes boxed warnings for progressive multifocal leukoencephalopathy (PML) and hepatitis B virus reactivation.

Background & Context

PMN is a rare autoimmune disease where the immune system attacks the kidney's glomeruli, leading to protein leakage into the urine. In the US, the estimated incidence is 1.2 per 100,000 people per year. Prior to this approval, clinicians relied on off-label therapies, such as tacrolimus. Obinutuzumab, an anti-CD20 monoclonal antibody, targets tissue-resident B cells to address the underlying cause of the disease.

Significance & Outlook

This approval fills a critical gap in care for a condition where approximately 30% of untreated patients progress to kidney failure within a decade. Obinutuzumab previously received breakthrough therapy, orphan drug, and priority review designations for this indication.

Source: https://www.ajmc.com/view/fda-approves-obinutuzumab-as-first-therapy-for-membranous-nephropathy

Collected: November 21, 2026 | Automated Research System (AI)

#06 64Cu-SAR-bisPSMA: FDA Breakthrough Designation and Clinical Data

Published November 17, 2026 CancerNetwork USA



OVERVIEW

The FDA has granted breakthrough therapy designation to 64Cu-SAR-bisPSMA for PSMA PET imaging in men with suspected biochemical recurrence of prostate cancer. Clinical data shows the agent detects significantly more lesions than 68Ga-PSMA-11, with 78% patient-level positivity compared to 36%. This designation accelerates the development of a bivalent imaging agent capable of extended imaging windows due to the 12.7-hour half-life of copper-64.

IN DEPTH

Key Findings

64Cu-SAR-bisPSMA has received FDA breakthrough therapy designation, marking the first such designation for a PSMA PET imaging agent. In the investigator-initiated Co-PSMA trial involving 50 patients with biochemical recurrence (BCR) and a median PSA of 0.43 ng/mL, 64Cu-SAR-bisPSMA imaging performed 24 hours after injection detected a mean of 1.26 lesions per patient, compared to 0.48 lesions with 68Ga-PSMA-11 (P <.0001). Patient-level positivity was 78% for 64Cu-SAR-bisPSMA versus 36% for 68Ga-PSMA-11, leading to changes in planned management for 44% of patients.

Technical Details

The agent is a bivalent molecule linking two PSMA-targeting molecules to a sarcophagine (SAR) chelator, designed to prevent copper leakage into the body. A critical technical advantage is the use of copper-64, which has a half-life of 12.7 hours. This allows for imaging up to approximately 30 hours post-injection, whereas gallium-68 and fluorine-18 have half-lives of only 1 to 2 hours. Additionally, the SAR platform is compatible with copper-67 for therapeutic applications.

Background and Context

The COBRA trial, focusing on patients with BCR and negative or equivocal conventional imaging (median PSA 0.9 ng/mL), found that next-day imaging identified approximately 91% more lesions than same-day imaging. For comparison, FDA labeling for 68Ga-PSMA-11 and 18F-DCFPyL reports positivity rates of 36% and 35%, respectively, in patients with BCR and PSA levels below 0.5 ng/mL.

Significance and Outlook

Clarity Pharmaceuticals is advancing two phase 3 trials to support an FDA application. The AMPLIFY trial, which reached its target of approximately 220 patients in March 2026, evaluates the agent in patients with PSA >0.2 ng/mL. The CLARIFY trial, which reached target enrollment in October 2026, evaluates high-risk prostate cancer patients before radical prostatectomy. Topline data from both trials are expected in the first half of 2027.

Source: https://www.cancernetwork.com/view/64cu-sar-bispsma-earns-fda-breakthrough-designation-in-recurrent-prostate-cancer

Collected: November 21, 2026 | Automated Research System (AI)

#07 iSCIB1+: Scancell's RMAT designation and Phase 3 timeline

Published November 19, 2026 Targeted Oncology USA



OVERVIEW

The FDA has granted Regenerative Medicine Advanced Therapy (RMAT) designation to iSCIB1+, a DNA-based immunotherapy for advanced melanoma. Phase 2 SCOPE data showed a 24-month overall survival rate of 87% for the iSCIB1+ cohort, supporting a global phase 3 trial scheduled to enroll its first patient in December 2026.

IN DEPTH

Key Findings

The FDA has granted RMAT designation to iSCIB1+, an investigational DNA-based immunotherapy developed by Scancell for advanced melanoma. This designation, which builds upon a previous fast track designation, allows for closer FDA interaction and potential eligibility for rolling review, priority review, and accelerated approval. In the Phase 2 SCOPE trial (NCT04079166), the iSCIB1+ cohort achieved a 24-month overall survival (OS) rate of 87%, compared to 82% across combined SCIB1 and iSCIB1+ cohorts (n=80).

Technical Details

iSCIB1+ is a DNA ImmunoBody therapy delivered via needle-free intramuscular injection. The vaccine encodes antibody constructs targeting melanoma-associated antigens gp100 and TRP-2 to prime high-avidity T cells. It is designed for use in combination with the checkpoint inhibitors ipilimumab and nivolumab. Technical data from the SCOPE trial indicates:

- **Progression-Free Survival (PFS):** In the HLA-targeted population, the 24-month PFS rate was 71% for the iSCIB1+ cohort and 65% for the combined cohorts. This compares to a 41.5% 24-month PFS rate reported in the CheckMate 067 trial for ipilimumab plus nivolumab.
- **Response Rates:** The complete response rate reached 31% in the iSCIB1+ cohort (cohort 3) and 28% across combined cohorts.
- **Safety:** The combination therapy demonstrated a 77% PFS rate at 22 months in the target HLA population without apparent additive checkpoint-related toxicity.

Background & Context

The development of iSCIB1+ has progressed following FDA clearance of the investigational new drug (IND) application and clinical trial authorization from the UK Medicines and Healthcare products Regulatory Agency earlier in 2026. Scancell intends to hold a multidisciplinary meeting with the FDA to align the manufacturing approach and the design of the phase 3 registrational trial.

Significance & Outlook

The RMAT designation recognizes the potential of iSCIB1+ to address unmet needs in advanced melanoma. Scancell expects to report more mature PFS findings and interim OS data in the first half of 2027. The global phase 3 trial remains on track to begin patient enrollment in December 2026.

Source: https://www.targetedonc.com/view/fda-grants-rmat-designation-iscib1-advanced-melanoma

Collected: November 21, 2026 | Automated Research System (AI)

#08 Belzutifan plus Lenvatinib: CHMP positive opinion for ccRCC

Published November 16, 2026 CancerNetwork USA



OVERVIEW

The EMA's CHMP has recommended the combination of belzutifan and lenvatinib for advanced clear cell renal cell carcinoma (ccRCC) following anti-PD-(L)1 therapy. Based on phase 3 LITESPARK-011 data, the regimen significantly improved progression-free survival compared to cabozantinib. This represents a potential first-of-its-kind combination of a HIF-2α inhibitor and a multitargeted VEGFR tyrosine kinase inhibitor in the EU.

IN DEPTH

Key Findings

The combination of belzutifan and lenvatinib demonstrated a significant improvement in progression-free survival (PFS) compared to cabozantinib, reducing the risk of progression or death by 26% (HR, 0.74; 95% CI, 0.61-0.89; P = 0.001). Median PFS was 14.6 months for the combination versus 10.6 months for cabozantinib. While overall survival (OS) did not reach statistical significance (HR, 0.85; 95% CI, 0.70-1.03), the median OS was 33.7 months for the combination compared to 28.6 months for the control group.

Additional efficacy data presented at the 2026 ESMO Congress showed an objective response rate (ORR) of 53.1% for the combination versus 40.2% for cabozantinib. The median duration of response (DOR) was 22.0 months compared to 11.9 months.

Technical Details

The LITESPARK-011 trial was a randomized, open-label, phase 3 study involving 747 patients with locally advanced or metastatic ccRCC who progressed on or after a PD-1 or PD-L1 inhibitor, or within 6 months of completing adjuvant PD-1 inhibitor therapy. The treatment arms were:

- Belzutifan 120 mg once daily plus lenvatinib 20 mg once daily.
- Cabozantinib 60 mg once daily.

Safety data for the combination therapy indicated that anemia occurred in 87% of patients, with 20% experiencing grade 3 events or requiring transfusion. Hypoxia occurred in 16% of patients (12% grade 3 or 4), and grade 3 or higher cardiac dysfunction occurred in 6%. Serious adverse reactions were reported in 54% of patients, and fatal reactions occurred in 5%.

Background and Regulatory Status

The CHMP's positive opinion follows the US FDA's approval of the combination for adults with advanced ccRCC following a PD-1 or PD-L1 inhibitor on September 24, 2026. The regimen targets a patient population with limited treatment options in the EU.

Significance and Outlook

If approved by the EMA, this regimen will be the first combination of a HIF-2α inhibitor and a multitargeted VEGFR tyrosine kinase inhibitor available in the European Union, providing a new therapeutic option for advanced renal cell carcinoma.

Source: https://www.cancernetwork.com/view/belzutifan-plus-lenvatinib-earns-positive-chmp-opinion-in-advanced-ccrcc

Collected: November 21, 2026 | Automated Research System (AI)

#09 Baxfendy: AstraZeneca's ASI for uncontrolled hypertension in EU

Published November 16, 2026 EuropaWire UK



OVERVIEW

AstraZeneca's Baxfendy (baxdrostat) has received a positive CHMP opinion for treating adults in the EU with arterial hypertension insufficiently controlled by at least two medicines. Phase III trials demonstrated significant reductions in systolic blood pressure, positioning the drug to become the first and only aldosterone synthase inhibitor in the EU.

IN DEPTH

Key Findings

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of Baxfendy (baxdrostat) for adults with arterial hypertension that remains insufficiently controlled despite the use of at least two antihypertensive medicinal products. If approved, Baxfendy will be the first and only aldosterone synthase inhibitor (ASI) available in the European Union.

Technical Details

The recommendation is based on data from two pivotal Phase III studies, BaxHTN and Bax24. In these trials, a 2 mg dose of Baxfendy demonstrated the following results at week 12:

- **BaxHTN:** Reduced mean seated systolic blood pressure (SBP) by 15.7 mmHg from baseline, with a placebo-adjusted reduction of 9.8 mmHg.
- **Bax24:** Reduced 24-hour average ambulatory SBP by 16.6 mmHg from baseline, with a placebo-adjusted reduction of 14.0 mmHg.

Baxfendy targets aldosterone directly to address a biological cause of elevated blood pressure. The trials reported that the drug was generally well tolerated with no unanticipated safety findings.

Background & Context

Hypertension affects 1.4 billion people globally, and approximately 70 million adults in Europe have uncontrolled hypertension despite treatment. High aldosterone levels contribute to this condition and are linked to increased cardiovascular risk and deteriorating kidney function. Epidemiological data indicates that a 10 mmHg decrease in SBP is associated with a roughly 20% lower risk of serious cardiovascular events, such as stroke and heart attack.

Significance & Outlook

Baxfendy is already approved in the United States and other countries for adults with hypertension not adequately controlled on other therapies. Regulatory filings are currently under review in other major regions, including China and Japan. The EU approval would provide a new class of treatment for the approximately half of patients receiving two or more antihypertensive medicines who still experience persistently uncontrolled hypertension.

Source: https://news.europawire.eu/astrazenecas-baxfendy-receives-positive-chmp-opinion-for-uncontrolled-hypertension-in-the-eu/eu-press-release/2026/11/16/13/52/05/188047/

Collected: November 21, 2026 | Automated Research System (AI)

#10 BHV-1530: Biohaven's FGFR3-Directed ADC Phase 1 Clinical Data

Published November 19, 2026　Yahoo Finance（Biohavenプレスリリース）　USA



OVERVIEW

Biohaven's BHV-1530, a first-in-class FGFR3-directed antibody-drug conjugate (ADC), demonstrated clinical activity and confirmed responses in FGFR3-altered urothelial and head and neck cancers. In patients with activating FGFR3 alterations treated at $\ge$3.3 mg/kg, 6 of 10 responded, including all 3 patients with HPV-positive HNSCC.

IN DEPTH

Key Findings

Phase 1 data presented at the 38th EORTC-NCI-AACR Symposium (ENA 2026) show that BHV-1530 achieved deep and durable responses in patients with FGFR3-altered urothelial cancer (UC) and head and neck squamous cell carcinoma (HNSCC). Among 10 efficacy-evaluable patients with activating FGFR3 alterations treated at doses of 3.3 mg/kg or higher, 9 of 10 showed tumor reduction and 6 achieved a partial response (PR). Specifically, responses were observed in 3 of 5 patients with UC and 3 of 3 patients with HPV-positive HNSCC. All responders remained on treatment as of the October 19, 2026, data cutoff, with some continuing beyond 6 months.

Technical Details

BHV-1530 is an ADC utilizing a proprietary topoisomerase I (TopoIx) payload. In a cohort of 30 patients receiving monotherapy every three weeks (Q3W) at doses from 1.0 to 12.0 mg/kg, the drug was well tolerated. Key safety data include:

- No dose-limiting toxicities (DLTs), treatment-related serious adverse events (SAEs), or treatment-related deaths.
- No reported cases of interstitial lung disease (ILD).
- Absence of typical FGFR class toxicities, such as hyperphosphatemia, nail dystrophy, or central serous retinopathy.
- Most common adverse events were Grade 1 or 2 nausea (43%) and fatigue (37%).

Pharmacokinetic analysis indicates high stability in circulation, with a half-life of 7 to 14 days and free payload exposure remaining below 1% of ADC exposure.

Background and Context

The study included highly refractory patients; all UC patients had progressed on enfortumab vedotin plus pembrolizumab (EV+P), and some had failed oral FGFR tyrosine kinase inhibitors. One highlighted case involved a patient with HPV-positive metastatic HNSCC (FGFR3 S249C mutation) who had failed four prior lines of therapy; this patient achieved a confirmed PR, with target lesions reducing by 67% at Week 6 and 86% by Week 24.

Significance and Outlook

Following an FDA Type C meeting in 4Q 2026, Biohaven plans to initiate a pivotal study for BHV-1530 in FGFR3-altered tumors, starting with UC. This study is expected to begin as early as 1H 2027 to support potential accelerated approval.

Source: https://finance.yahoo.com/healthcare/articles/biohavens-novel-fgfr3-directed-adc-123000296.html

Collected: November 21, 2026 | Automated Research System (AI)

#11 Corxel US CX11: Phase 2 Weight Loss Results and Safety Profile

Published November 16, 2026　Yahoo Finance（Corxelプレスリリース）　USA



OVERVIEW

Corxel US reported that its oral GLP-1 receptor agonist CX11 achieved mean weight loss of 9.3% to 11.5% over 36 weeks in adults with overweight and obesity. The trial showed no weight plateau and a safety profile consistent with the GLP-1 RA class, providing a foundation for upcoming global Phase 3 studies.

IN DEPTH

Key Findings

In a U.S. Phase 2 trial, once-daily oral CX11 demonstrated clinically meaningful weight loss across all four dose regimens. At 36 weeks, participants experienced a mean weight loss of 9.3% to 11.5%, compared to 3.1% for the placebo group ($P<0.0001$). Up to 89% of CX11-treated participants achieved at least 5% weight loss, and up to 66% reached at least 10%, whereas placebo rates were 44% and 12%, respectively.

Technical Details

The randomized, double-blind, placebo-controlled trial (CX11201; NCT07011797) enrolled 246 adults with obesity (BMI ≥30 kg/m²) or overweight (BMI ≥27 kg/m²) with at least one weight-related comorbidity. Participants were randomized 1:1:1:1:1 to receive placebo or CX11 at 120 mg, 160 mg, 200 mg (fast titration), or 200 mg (slow titration). The primary endpoint was percent change in body weight at week 26, where CX11 doses produced mean weight loss of 8.0% to 9.0% versus 2.8% for placebo ($P<0.0001$).

Additional metrics at week 36 included:

- Waist circumference reduction: 8.3 to 11.5 cm for CX11 vs. 3.4 cm for placebo.
- BMI reduction: 3.3 to 4.3 kg/m² for CX11 vs. 1.1 kg/m² for placebo.

Safety data indicated that gastrointestinal (GI) events were mostly mild to moderate and concentrated during dose escalation through week 16. Nausea occurred in 32.7% to 34.0% of CX11 participants versus 10.9% for placebo. Discontinuation due to GI events was 5.0% for CX11 and 2.2% for placebo. No hepatic safety signals were identified, and no participants met Hy's law criteria.

Background and Outlook

CX11 is an oral small molecule GLP-1 receptor agonist acquired by Corxel US from Vincentage in December 2024 for global rights excluding China. The molecule is designed to provide a scalable, convenient alternative to injectable GLP-1 RAs for treating obesity, overweight, and type 2 diabetes. Following these Phase 2 results and alignment with the FDA, Corxel US plans to advance CX11 into pivotal global Phase 3 clinical trials.

Source: https://finance.yahoo.com/healthcare/articles/corxel-us-presents-full-phase-133400036.html

Collected: November 21, 2026 | Automated Research System (AI)

#12 HUTCHMED SYVIK: China NMPA Approval for ITP and wAIHA

Published November 19, 2026 Markets Insider（GlobeNewswire） China



OVERVIEW

HUTCHMED has received simultaneous approval from China's NMPA for SYVIK (sovleplenib), the first novel oral Syk inhibitor approved in China. The drug is indicated for adult patients with primary immune thrombocytopenia (ITP) and warm antibody autoimmune hemolytic anemia (wAIHA) who showed insufficient response to prior therapies.

IN DEPTH

Key Findings

The China National Medical Products Administration (NMPA) has approved SYVIK (sovleplenib) for two autoimmune indications: chronic primary ITP in adults with insufficient response to at least one prior therapy, and wAIHA in adults with insufficient response to prior corticosteroid therapy. This marks HUTCHMED's first in-house discovered immunology drug to reach commercialization, expanding the company's portfolio beyond oncology.

Technical Details

SYVIK is a selective oral small molecule inhibitor targeting spleen tyrosine kinase (Syk). Its efficacy was evaluated through two pivotal trials:

- **ESLIM-01 (ITP):** In a randomized, double-blind, placebo-controlled Phase III trial of 188 adults, SYVIK showed a durable response rate of 48.4% compared to 0% for placebo ($p < 0.0001$). Overall response rates were 68.3% (0–12 weeks) and 70.6% (0–24 weeks), versus 14.5% and 16.1% for placebo ($p < 0.0001$).
- **ESLIM-02 (wAIHA):** In a Phase II/III study of adults relapsed or refractory to glucocorticoids, SYVIK achieved a durable response rate of 66% during weeks 5–24, compared to 15% for placebo ($p < 0.0001$). The overall response rate (hemoglobin ≥100 g/L with an increase of ≥20 g/L from baseline) was 70% for SYVIK versus 22% for placebo ($p < 0.0001$).

Background & Context

ITP is an autoimmune disorder where platelets are destroyed via Syk-dependent phagocytosis of FcγR-bound platelets, leading to bleeding risks and fatigue. The prevalence of primary ITP in China is estimated at approximately 110,000 patients. wAIHA is characterized by the production of antibodies against red blood cells. Both conditions often face challenges with disease relapse and the tolerability of prolonged standard treatments.

Significance & Outlook

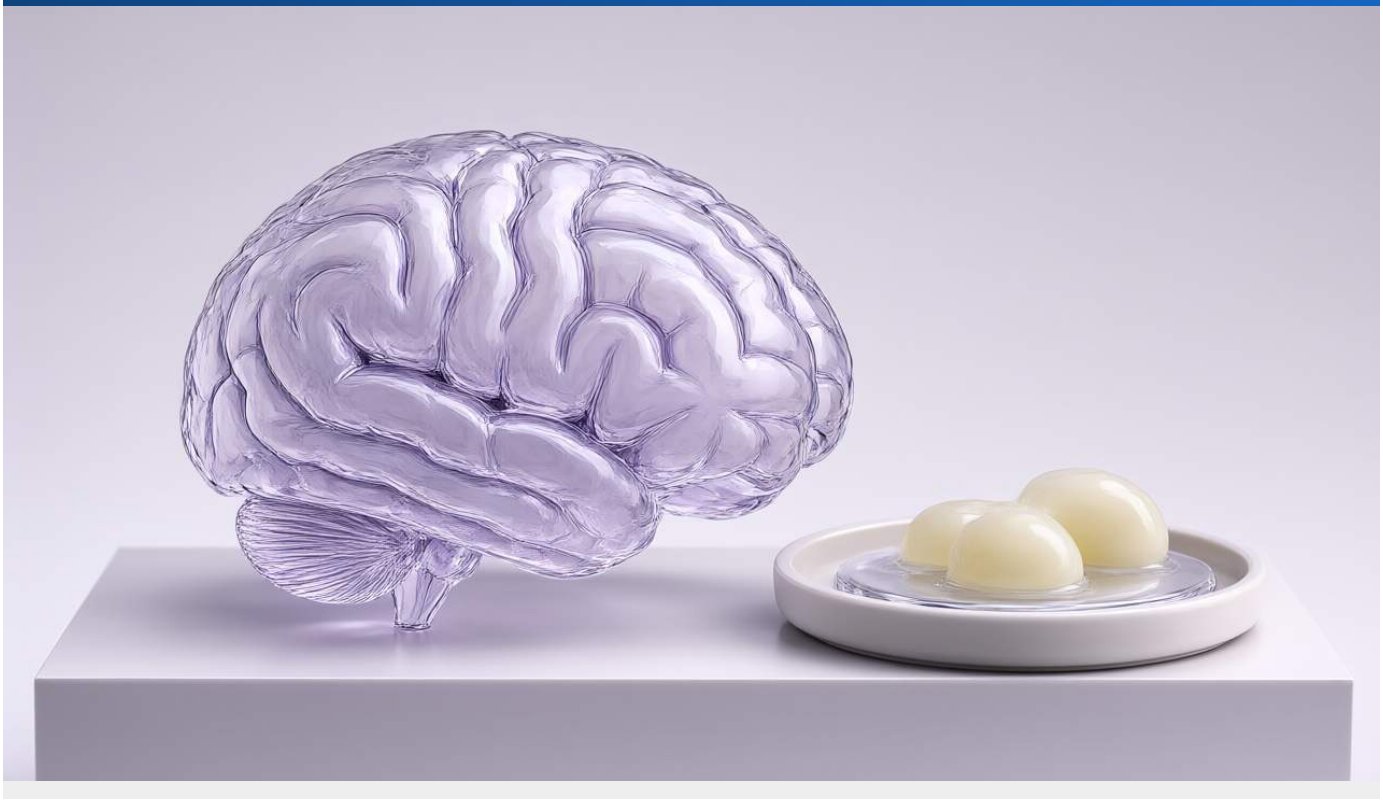
Beyond China, the US FDA granted sovleplenib Orphan Drug Designation in October 2026 for primary ITP and autoimmune hemolytic anemia. HUTCHMED retains full worldwide rights to the compound and is currently evaluating strategic pathways for global development.

Source: https://markets.businessinsider.com/news/stocks/hutchmed-announces-china-nmpa-approval-of-syvik-sovleplenib-for-the-treatment-of-primary-immune-thrombocytopenia-and-warm-antibody-autoimmune-hemolytic-anemia-1036783084

Collected: November 21, 2026 | Automated Research System (AI)

#13 Priavoid PRI-002: Phase 2 Alzheimer's Data and CTAD 2026 Results

Published November 17, 2026 Markets Insider（GlobeNewswire） Germany



OVERVIEW

Priavoid's Phase 2 trial of the oral all-D-peptide PRI-002 met its primary safety endpoint but failed to meet its primary efficacy endpoint (CDR-SB) at Week 48. However, the study showed a 35.9% slowing of cognitive decline on ADAS-Cog at Week 72 in the per protocol population (p=0.022), suggesting potential as a disease-modifying treatment.

IN DEPTH

Key Findings

Priavoid reported topline results from the PRImus-AD Phase 2 trial, which evaluated PRI-002 in patients with early Alzheimer's disease (AD). While the primary efficacy endpoint—measured by the change from baseline in the Clinical Dementia Rating - Sum of Boxes (CDR-SB) at Week 48—was not met, the drug demonstrated a favorable safety and tolerability profile. Positive clinical signals were observed in cognition and daily functioning, with effects becoming more pronounced over time.

Technical Details

The randomized, double-blind, placebo-controlled study enrolled 304 patients with MCI or mild dementia due to AD, randomized 1:1:1 to receive 300 mg daily, 600 mg daily, or placebo. The trial used a common-close design with treatment durations between 48 and 96 weeks.

- **Safety:** ARIA-E (edema) occurred in 2% of the 300 mg group, 0% of the 600 mg group, and 1% of the placebo group. ARIA-H (hemorrhage) was observed in 8%, 11.7%, and 5% of these groups, respectively. Common adverse events included nausea, dizziness, and headache.
- **Cognitive Efficacy:** In the per protocol population at Week 72, ADAS-Cog showed a 35.9% slowing of decline (p=0.022). In the mITT population at Week 72, the slowing was 26.7% (p=0.102).
- **Functional Efficacy:** At Week 72, the ADCS-ADL showed a 30.4% difference favoring PRI-002 in the per protocol population (p=0.080) and a 27.1% difference in the mITT population (p=0.120).

Background and Context

PRI-002 is a first-in-class oral all-D-peptide compound designed to disassemble neurotoxic amyloid-beta (Aβ) oligomers. The topline findings were presented by Prof. Dr. Oliver Peters at the 2026 Clinical Trials on Alzheimer's Disease (CTAD) conference in Boston. The study was funded by SPRIND.

Significance and Outlook

The preliminary biomarker observations and the statistical significance reached in the ADAS-Cog per protocol population support the further clinical development of PRI-002. Priavoid expects to present the full dataset, including comprehensive safety and biomarker analyses, in 2027.

Source: https://markets.businessinsider.com/news/stocks/priavoid-announces-topline-phase-2-data-for-oral-all-d-peptide-pri-002-in-alzheimer-s-disease-at-ctad-2026-1036774435

Collected: November 21, 2026 | Automated Research System (AI)

#14 SELLAS Life Sciences: GPS Phase 3 REGAL trial OS results for AML

Published November 17, 2026 The Globe and Mail（GlobeNewswire） USA



OVERVIEW

The Phase 3 REGAL trial of the immunotherapeutic cancer vaccine galinpepimut-S (GPS) demonstrated a 41% reduction in the risk of death compared to the best available treatment in AML patients. Median overall survival increased to 24.0 months from 14.7 months, providing a potential new maintenance therapy for high-risk patients ineligible for stem cell transplantation.

IN DEPTH

Key Findings

The pivotal randomized Phase 3 REGAL trial met its primary endpoint of overall survival (OS). Patients treated with galinpepimut-S (GPS) showed a median OS of 24.0 months, compared to 14.7 months for those receiving the investigator's choice of best available treatment (BAT). This represents a 41% reduction in the risk of death, with a hazard ratio of 0.59 and a two-sided p-value of 0.035.

Technical Details

The trial evaluated GPS as a maintenance monotherapy for patients with acute myeloid leukemia (AML) who achieved a second or later complete remission (CR2 or later) or complete remission with insufficient platelet recovery (CRp2 or later) following second- or later-line salvage therapy. The study specifically targeted patients who were unable to undergo or ineligible for allogeneic stem cell transplantation. The topline analysis was conducted after the occurrence of 80 deaths, per the pre-specified statistical analysis plan (SAP).

Regarding safety, GPS was generally well tolerated with no new safety signals. Treatment-related adverse events were primarily grade 1/2, with local injection site reactions being the most common. Prognostic stratification factors were well balanced between the study and control arms, and the limited number of patients who proceeded to hematopoietic stem cell transplantation were equally distributed across both groups.

Background & Context

GPS is a WT1-targeted immunotherapeutic cancer vaccine designed to train the immune system to target residual leukemia cells. This population of AML patients in second remission who cannot undergo transplantation typically faces poor survival outcomes and has significant unmet medical needs.

Significance & Outlook

SELLAS Life Sciences plans to meet with the U.S. Food and Drug Administration (FDA) to discuss an accelerated filing strategy. The company is preparing a Biologics License Application (BLA) submission for GPS, targeted for the first half of 2027. Comprehensive evaluations of secondary endpoints and additional pre-specified analyses are currently underway for future publication in a peer-reviewed journal and presentation at a medical conference.

Source: https://www.theglobeandmail.com/investing/markets/markets-news/GlobeNewswire/8872029/sellas-life-sciences-announces-positive-pivotal-phase-3-regal-trial-data-showing-immunotherapeutic-cancer-vaccine-galinpepimut-s-gps-demonstrated-a-statistically-significant-and-clinically-meaningful-improvement-in-overall-survival-in-patients/

#15 Leqembi: 3-Year Real-World Data on Alzheimer's Progression and Safety

Published November 18, 2026　PR Newswire（BioArctic）　スウェーデン



OVERVIEW

Real-world data from the LEADER study shows that Leqembi reduced the rate of progression to moderate or severe Alzheimer's dementia by 76% over 36 months compared to a matched cohort. The findings, presented at CTAD 2026, indicate high treatment persistence and lower ARIA rates in clinical practice than in Phase 3 trials.

IN DEPTH

Key Findings from the LEADER Study

Patients treated with Leqembi demonstrated a 76% lower rate of progression to moderate or severe Alzheimer's disease dementia over 36 months compared to an ADNI-weighted external control cohort (HR 0.24; 95% CI, 0.15–0.39). Among 546 patients assessed after an average of 18 months, 81.1% were reported as stable or improved, with 75.8% remaining stable and 5.3% showing improvement. Statistical modeling suggests 95.0% of the 560 total patients remained in the early stages of the disease through three years of treatment.

Technical Details and Maintenance Therapy

Amyloid clearance was observed in 77% of 43 patients who underwent baseline and follow-up PET scans, with a median follow-up of 18.1 months. Regarding maintenance therapy, 218 patients transitioned to intravenous (IV) treatment every four weeks, while 64 transitioned to once-weekly subcutaneous (SC) maintenance. Stability rates were 71.1% for monthly IV and 76.6% for weekly SC maintenance after average durations of 26 and 25.1 months, respectively. All 64 patients on SC maintenance remained on therapy at the time of chart extraction.

Safety and ARIA Incidence

Safety data showed that ARIA-E occurred in 6.6% of LEADER patients, compared to 6.3% in the ALZ-NET registry. No ARIA events were reported during the SC maintenance period. A separate meta-analysis of approximately 5,000 patients across six countries revealed a pooled total ARIA rate of 12.4%, which is lower than the 21.5% reported in the Phase 3 Clarity AD study. Symptomatic ARIA was reported in 0.8% of these patients, compared to 2.8% in Clarity AD.

Context and Limitations

The results were generally consistent across sex, race, ethnicity, APOE genotype, and antithrombotic use. However, the authors note that as a retrospective real-world study, the data is subject to limitations including potential biases, lack of a placebo-controlled arm, and data inconsistency.

Source: https://www.prnewswire.com/news-releases/new-three-year-real-world-data-on-leqembi-presented-at-ctad-2026-302944141.html

Collected: November 21, 2026 | Automated Research System (AI)

#16 Acoramidis: ATTR-CM outcomes vs tafamidis and placebo in 2026

Published November 17, 2026 Markets Insider（GlobeNewswire） USA



OVERVIEW

Acoramidis demonstrated a 45% reduction in the risk of first heart failure (HF) events versus placebo and a 23% lower risk of oral diuretic intensification compared to tafamidis in real-world data. These results indicate rapid onset of benefit within one month and durable reductions in HF mortality. The data suggests acoramidis provides broad clinical advantages for patients with transthyretin amyloid cardiomyopathy (ATTR-CM).

IN DEPTH

Key Findings

Acoramidis significantly reduced the risk of a first HF-specific event by 45% versus placebo through Month 30 (HR 0.55; 95% CI 0.44-0.69; p<0.001), with benefits emerging within the first month of treatment. By Month 30, the incidence of HF-specific events was 48.2% for acoramidis compared to 67.3% for placebo (number needed to treat=6). Furthermore, continuous treatment was associated with a 58% lower risk of HF death through Month 54 compared to patients who started treatment later (HR 0.42; 95% CI 0.27-0.65; p<0.001).

Technical Details

The ATTRibute-CM trial showed acoramidis lowered the rate of all HF event types:

- HF hospitalization ≥24 hours: 13.0% vs 25.7% (placebo)
- HF mortality: 9.0% vs 13.9% (placebo)
- Urgent HF visit: 3.9% vs 6.4% (placebo)
- Outpatient worsening HF: 40.8% vs 59.4% (placebo)

Regarding renal safety, analyses indicated that an early eGFR dip associated with kidney-protective activity was consistent regardless of baseline AF status, diabetes status, RAAS inhibitor use, or genotype. In participants with CKD stage 4, kidney function remained stable over 30 months without clinically meaningful changes in safety markers.

Real-World Evidence and Context

The Bayer-led mODIficATTR study in Germany followed 488 treatment-naive individuals starting acoramidis and 659 starting tafamidis from April 2025 through April 2026. Acoramidis was associated with a 23% lower risk of oral diuretic intensification (ODI), an early marker of worsening HF (adjusted HR 0.77; 95% CI 0.61–0.98; p=0.04). At 12 months, the cumulative risk of ODI was 35% for acoramidis versus 43% for tafamidis. Other real-world data included a 34% reduction in clinical worsening events (Wright et al.) and a 27% lower risk of cardiovascular hospitalization (Lanfear et al.).

Significance and Outlook

Acoramidis is the only selective, orally administered, near-complete (≥90%) TTR stabilizer. With 81.4% of newly treated ATTR-CM patients initiating TTR stabilizer monotherapy, these data highlight the speed and breadth of acoramidis' benefit in preventing urgent doctor visits, hospitalizations, and death.

Source: https://markets.businessinsider.com/news/stocks/acoramidis-was-associated-with-lower-risk-of-worsening-heart-failure-versus-tafamidis-in-real-world-study-and-reduced-heart-failure-events-within-one-month-in-attribute-cm-1036773552

Collected: November 21, 2026 | Automated Research System (AI)