TROY TECHNICAL

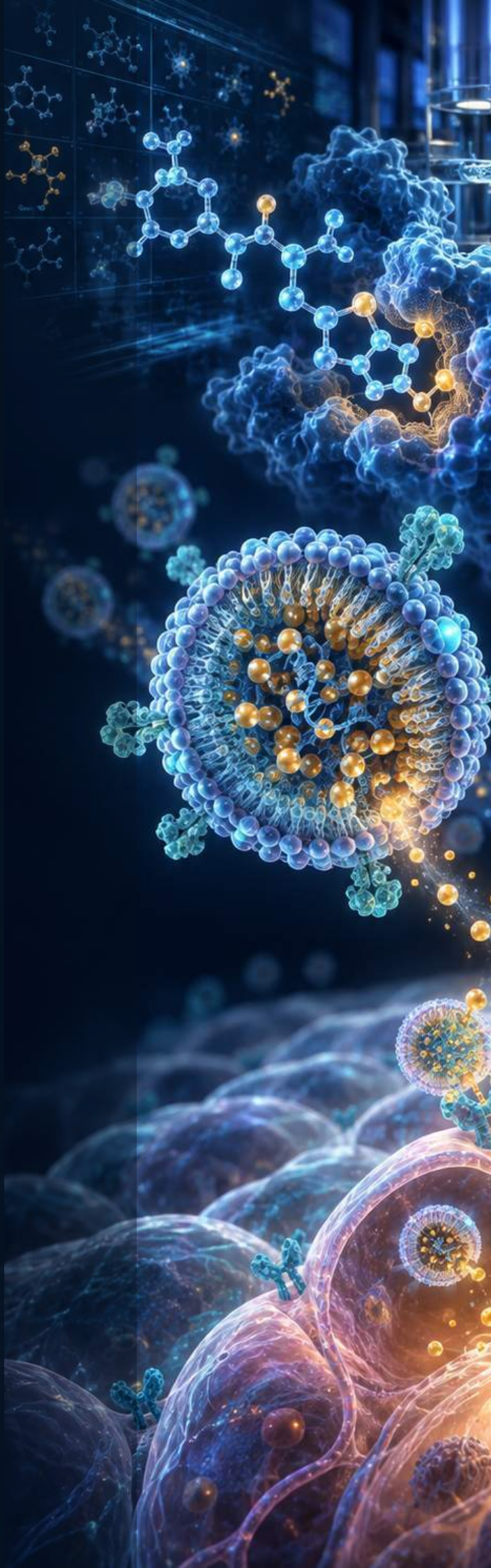
DRUG DISCOVERY & DDS
WEEKLY REPORT

November 8 - November 14, 2026 | Issue 2026-W45

Target validation, translational evidence, delivery and development economics

11	10
ANALYZED ARTICLES	PRIORITY THEMES

Issued 2026-11-14 | English edition | fixed approved cover artwork



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

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

SIGNAL 01 | TARGET & MOLECULE

Asundexian: FDA Approval and OCEANIC-STROKE Trial Results

The FDA has approved asundexian (Sunharbo), the first factor XIa inhibitor for the secondary prevention of noncardioembolic ischemic stroke and high-risk TIA.

SIGNAL 02 | DELIVERY DESIGN

Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC

The FDA has approved a perioperative regimen of durvalumab and enfortumab vedotin (EV) for adult patients with muscle-invasive bladder cancer (MIBC) ineligible for cisplatin.

SIGNAL 03 | PRECLINICAL PROOF

Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs

Codexis presented data at TIDES Europe 2026 showing its ECO Synthesis platform achieves over 90% product quality at a 100-gram scale while nearly halving cycle time.

SIGNAL 04 | CLINICAL DEVELOPMENT

X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing

Researchers have developed the X-Editor (XE), a compact nuclease platform derived from Cas12e that exhibits over 100-fold higher editing activity in human cells than its predecessor.

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

6.2%
A10

SOURCE-BOUND CONDITION
In phase 3 trials, a 50 mg daily dose combined with antiplatelet therapy reduced ischemic stroke incidence to 6.2% compared to 8.4% for placebo without a significant increase in major bleeding.

42%
A04

SOURCE-BOUND CONDITION
The combination reduced the risk of death by 42% and the risk of recurrence, progression, failure to undergo surgery, or death by 49% compared to surgery alone.

90%
A06

SOURCE-BOUND CONDITION
Codexis presented data at TIDES Europe 2026 showing its ECO Synthesis platform achieves over 90% product quality at a 100-gram scale while nearly halving cycle time.

100%
A11

SOURCE-BOUND CONDITION
Combination therapy with elebsiran and tobevibart achieved 100% undetectable viremia in patients completing 96 weeks of treatment for chronic hepatitis delta (CHD).

88%
A09

SOURCE-BOUND CONDITION
The therapy achieved an 88% DORIS remission rate at Month 12 in refractory SLE patients and demonstrated a superior immune reset compared to single-target CD19 approaches.

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 asundexian (Sunharbo) , the first factor XIa inhibitor for the secondary prevention of noncardioembolic.

2

Delivery design

P02/P07

The FDA has approved a perioperative regimen of durvaluma b and enfortumab vedotin (EV) for adult patients with.

3

Preclinical proof

P03/P08

Codexis presented data at TIDES Europe 2026 showing its ECO Synthesis platform achieves over 90% product quality at a.

4

Clinical development

P04/P09

Researchers have developed the X-Editor (XE), a compact nuclease platform derived from Cas12e that exhibits over 100-fold.

5

Access & portfolio

P05/P10

Combination therapy with elebsiran and tobevibart achieved 100% undetectable viremia in patients completing 96 weeks of.

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	Asundexian: FDA Approval and OCEANIC-STROKE Trial Results Business / rules | cue: FDA
P02	Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC Business / rules | cue: FDA
P03	Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs System / adoption | cue: platform
P04	X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing System / adoption | cue: platform
P05	Vir Biotechnology: Elebsiran and Tobevibart Phase 2 SOLSTICE Data System / adoption | cue: Phase 2
P06	ImvivaBio CTA313: Dual CD19/BCMA CAR-T Data for Lupus (2026) Tech / process | cue: no system/business cue
P07	PS-10 Molecular Glue: BTK Degradation and PPI Interface Specs Tech / process | cue: no system/business cue
P08	CIDEB siRNA: Regeneron's MASLD liver fat reduction trial results System / adoption | cue: trial
P09	tLNP Analysis: Multi-Attribute SE-HPLC for RNA and Antibody Quantification Business / rules | cue: standard
P10	GluePlex: Predicting CRBN-Neosubstrate Ternary Complex Structures Tech / process | cue: no system/business cue

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 Asundexian: FDA Approval and OCEANIC-STROKE Trial Results

A10 | Target & molecule | Scale-up

2026-11-09

FACT

The FDA has approved asundexian (Sunharbo), the first factor XIa inhibitor for the secondary prevention of noncardioembolic ischemic stroke and high-risk TIA. In phase 3 trials, a 50 mg daily dose combined with antiplatelet therapy reduced ischemic stroke incidence to 6.2% compared to 8.4% for placebo without a significant increase in major bleeding.

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 20/25 | MATURITY 5/5 | DECISION LOCUS: BUSINESS / RULES

P02 Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC

A04 | Delivery design | Scale-up

2026-11-13

FACT

The FDA has approved a perioperative regimen of durvalumab and enfortumab vedotin (EV) for adult patients with muscle-invasive bladder cancer (MIBC) ineligible for cisplatin. The combination reduced the risk of death by 42% and the risk of recurrence, progression, failure to undergo surgery, or death by 49% compared to surgery alone. This provides a new standard of care for a patient population that previously had poor prognoses with radical cystectomy alone.

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 20/25 | MATURITY 5/5 | DECISION LOCUS: BUSINESS / RULES

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

P03 Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs

A06 | Preclinical proof | Product adoption

2026-11-09

FACT

Codexis presented data at TIDES Europe 2026 showing its ECO Synthesis platform achieves over 90% product quality at a 100-gram scale while nearly halving cycle time. The platform also demonstrated a 3- to 4-fold increase in potency in human hepatocyte in vitro models compared to traditional chemical synthesis. These results indicate a scalable, enzymatic alternative to solid phase organic synthesis for RNAi therapeutics.

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 4/5 | DECISION LOCUS: SYSTEM / ADOPTION

P04 X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing

A03 | Clinical development | Pilot

2026-11-12

FACT

Researchers have developed the X-Editor (XE), a compact nuclease platform derived from Cas12e that exhibits over 100-fold higher editing activity in human cells than its predecessor. Tested in nonhuman primate livers via lipid nanoparticles, XE achieved greater editing at lower doses than comparable Cas9-based therapies currently in clinical testing. This advancement enables high-potency genome editing with stringent specificity, reducing off-target risks for genetic medicines.

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 2/5 | DECISION LOCUS: SYSTEM / ADOPTION

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

P05 Vir Biotechnology: Elebsiran and Tobevibart Phase 2 SOLSTICE Data

A11 | Access & portfolio | Research

2026-11-08

FACT

Combination therapy with elebsiran and tobevibart achieved 100% undetectable viremia in patients completing 96 weeks of treatment for chronic hepatitis delta (CHD). Exploratory data suggests curative potential, with all ten patients who discontinued treatment achieving SVR12. These results support a planned global regulatory filing for the U.S. FDA in mid-2027.

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: SYSTEM / ADOPTION

P06 ImvivaBio CTA313: Dual CD19/BCMA CAR-T Data for Lupus (2026)

A09 | Target & molecule | Research

2026-11-11

FACT

ImvivaBio presented 12-month follow-up data for CTA313, an allogeneic dual-targeted CD19/BCMA CAR-T therapy for systemic lupus erythematosus (SLE) and lupus nephritis (LN). The therapy achieved an 88% DORIS remission rate at Month 12 in refractory SLE patients and demonstrated a superior immune reset compared to single-target CD19 approaches. These results support the transition to a global Phase 1b ALLNEW basket study.

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 19/25 | MATURITY 1/5 | DECISION LOCUS: TECH / PROCESS

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

P07 PS-10 Molecular Glue: BTK Degradation and PPI Interface Specs

A07 | Delivery design | Pilot

Prior release 2026-11-06

FACT

Researchers have discovered PS-10, the first molecular glue targeting Bruton's tyrosine kinase (BTK), which achieves a DC 50 in the single-digit nanomolar range and a D max exceeding 95%. The molecule utilizes a plastic protein-protein interaction (PPI) interface rather than rigid degrons, providing a new blueprint for rational molecular glue design.

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 19/25 | MATURITY 2/5 | DECISION LOCUS: TECH / PROCESS

P08 CIDEB siRNA: Regeneron's MASLD liver fat reduction trial results

A05 | Preclinical proof | Joint evaluation

2026-11-08

FACT

A single subcutaneous dose of CIDEB siRNA reduced liver fat by 58-80% and improved liver injury markers in MASLD patients through week 36. The trial demonstrated that 62% of recipients achieved normalized liver fat levels, suggesting a potential for twice-yearly dosing.

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 19/25 | MATURITY 3/5 | DECISION LOCUS: SYSTEM / ADOPTION

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

P09 tLNP Analysis: Multi-Attribute SE-HPLC for RNA and Antibody Quantification

A01 | Clinical development | Pilot

2026-11-09

FACT

Researchers have developed an online deformulating size-exclusion high-performance liquid chromatography (SE-HPLC) method to simultaneously quantify total RNA, conjugated antibody, and free antibody in targeted lipid nanoparticles (tLNPs). Using only 5 µL of sample, the method achieves spike recoveries of 88-122% and precision below 5% relative standard deviation. This approach streamlines the characterization of encapsulated cargo and surface ligands by reducing sample handling.

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 19/25 | MATURITY 2/5 | DECISION LOCUS: BUSINESS / RULES

P10 GluePlex: Predicting CRBN-Neosubstrate Ternary Complex Structures

A08 | Access & portfolio | Research

2026-11-11

FACT

GluePlex improves the prediction of novel cereblon (CRBN) ternary complexes by combining restrained protein-protein docking with template-guided Boltz-2 co-folding. In tests on novel pairs, it increased the number of acceptable poses to 23 of 39 runs with a median DockQ of 0.43, compared to 12 of 39 runs and a median DockQ of 0.01 for plain Boltz-2. This approach moves molecular-glue degrader design toward a more rational, rather than empirical, process.

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 19/25 | MATURITY 1/5 | DECISION LOCUS: TECH / PROCESS

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 01-11

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	tLNP Analysis: Multi-Attribute SE-HPLC for RNA and Antibody Quantification	https://doi.org/10.64898/2026.11.06.764440
A02	PIVOT: PAM-independent TIGR-Tas editor for AAV and LNP delivery	https://doi.org/10.21203/rs.3.rs-11118113/v1
A03	X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing	https://doi.org/10.64898/2026.11.10.765514
A04	Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC	https://www.ajmc.com/view/durvalumab-plus-enfortumab-vedotin-before-surgery-cuts-risk-of-death-42-in-cisplatin-ineligible-mibc
A05	CIDEB siRNA: Regeneron's MASLD liver fat reduction trial results	https://markets.ft.com/data/announce/full?dockey=1330-9872883en-3MNI6QMM7DHVQKKI3GI5AB6UVP
A06	Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs	https://markets.businessinsider.com/news/stocks/codexis-advances-eco-synthesis-toward-adoption-readiness-with-quality-at-scale-and-expanded-sirna-manufacturing-capabilities-1036736462
A07	PS-10 Molecular Glue: BTK Degradation and PPI Interface Specs	https://doi.org/10.21203/rs.3.rs-11296825/v1
A08	GluePlex: Predicting CRBN-Neosubstrate Ternary Complex Structures	https://doi.org/10.21203/rs.3.rs-11580478/v1
A09	ImvivaBio CTA313: Dual CD19/BCMA CAR-T Data for Lupus (2026)	https://finance.yahoo.com/healthcare/articles/imvivabio-presents-longer-term-data-130000771.html
A10	Asundexian: FDA Approval and OCEANIC-STROKE Trial Results	https://www.neurologylive.com/view/fda-approves-asundexian-treatment-secondary-stroke-prevention
A11	Vir Biotechnology: Elebsiran and Tobevibart Phase 2 SOLSTICE Data	https://www.aol.com/articles/vir-biotechnology-announces-expanded-phase-214500000.html

DrugDiscovery_DDS — Selected Articles

Date: 2026-11-15

Articles: 11

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#01 tLNP Analysis: Multi-Attribute SE-HPLC for RNA and Antibody Quantification

#02 PIVOT: PAM-independent TIGR-Tas editor for AAV and LNP delivery

#03 X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing

#04 Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC

#05 CIDEB siRNA: Regeneron's MASLD liver fat reduction trial results

#06 Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs

#07 PS-10 Molecular Glue: BTK Degradation and PPI Interface Specs

#08 GluePlex: Predicting CRBN-Neosubstrate Ternary Complex Structures

#09 ImvivaBio CTA313: Dual CD19/BCMA CAR-T Data for Lupus (2026)

#10 Asundexian: FDA Approval and OCEANIC-STROKE Trial Results

#11 Vir Biotechnology: Elebsiran and Tobevibart Phase 2 SOLSTICE Data

#01 tLNP Analysis: Multi-Attribute SE-HPLC for RNA and Antibody Quantification

Published November 09, 2026 bioRxiv USA



OVERVIEW

Researchers have developed an online deformulating size-exclusion high-performance liquid chromatography (SE-HPLC) method to simultaneously quantify total RNA, conjugated antibody, and free antibody in targeted lipid nanoparticles (tLNPs). Using only 5 µL of sample, the method achieves spike recoveries of 88-122% and precision below 5% relative standard deviation. This approach streamlines the characterization of encapsulated cargo and surface ligands by reducing sample handling.

IN DEPTH

Key Findings

The reported online deformulating SE-HPLC method enables the concurrent quantification of total RNA, conjugated antibody, and free antibody from a 5 µL tLNP sample. The system demonstrated a linear response across evaluated concentration ranges, with precision below 5% relative standard deviation and spike recoveries ranging from 88-122%. When applied to purified tLNP formulations, the method successfully assessed total RNA and conjugated antibody content while confirming that no detectable free antibody remained after purification.

Technical Details

The method utilizes a mobile phase containing sodium dodecyl sulfate and isopropanol to disrupt nanoparticles upon injection. This online deformulation allows for the chromatographic separation of RNA, conjugated antibodies, and unconjugated (free) antibodies. To optimize sensitivity, the system employs different detection methods for different analytes: RNA is quantified via UV260 detection, while antibodies are quantified using UV280 or intrinsic fluorescence detection.

Background and Context

Targeted lipid nanoparticles (tLNPs) are designed to improve the selective delivery of therapeutic payloads to specific cells and tissues. However, characterizing these particles is challenging because conventional nucleic acid and protein assays are often hindered by nanoparticle scattering and matrix interference. Furthermore, standard assays frequently struggle to distinguish between antibodies that are conjugated to the nanoparticle surface and those that remain free in the formulation.

Significance and Outlook

By integrating the disruption of nanoparticles directly into the HPLC process, this multi-attribute analytical method minimizes the sample handling required prior to analysis. The ability to use standard HPLC instrumentation for the simultaneous assessment of RNA and antibody concentrations provides a practical tool for the characterization of tLNP formulations. The authors of the study are employees of ModeX Therapeutics.

Source: https://doi.org/10.64898/2026.11.06.764440

Collected: November 15, 2026 | Automated Research System (AI)

#02 PIVOT: PAM-independent TIGR-Tas editor for AAV and LNP delivery

Published November 09, 2026 Research Square



OVERVIEW

Researchers have developed PIVOT, a hyper-compact, PAM-independent genome editor that achieves editing activity comparable to SpRY in mammalian cells. The system enables durable hepatic PCSK9 knockout via a single AAV vector and supports LNP delivery through a circularized tigRNA called Mobius.

IN DEPTH

Key Findings

The PIVOT (PAM-Independent Versatile and Optimized TIGR-Tas) editor demonstrates high specificity and editing activity in mammalian cells comparable to SpRY. In vivo applications using a single AAV vector resulted in durable hepatic PCSK9 knockout, which reduced circulating PCSK9 by ~82% and serum LDL-C by ~47%. Additionally, microinjection into mouse zygotes enabled efficient germline editing.

Technical Details

PIVOT was developed through iterative engineering based on deep mutational scanning of the TIGR-ParTasR nuclease and its cognate tigRNA. This process identified that intrinsic tigRNA instability and weak protein-nucleic acid contacts were the primary constraints on editing activity. To further enhance the system for lipid-nanoparticle (LNP) delivery, a covalently circularized tigRNA named Mobius was created to improve RNA stability. This PIVOT/Mobius combination provides a compact editor compatible with both LNP- and AAV-mediated delivery methods.

Background & Context

Therapeutic RNA-guided genome editors typically require a combination of broad genomic access and efficient delivery, but these two properties are rarely found together in existing nucleases. While tandem interspaced guide RNA (TIGR)-Tas systems are compact and PAM-independent, their editing activity has historically remained low, necessitating the optimizations that led to PIVOT.

Significance & Outlook

The development of PIVOT addresses the critical trade-off between nuclease size and genomic accessibility. By eliminating PAM dependence and reducing the system's footprint, PIVOT allows for the use of single AAV vectors for in vivo editing. The integration of the Mobius circularized tigRNA further expands the delivery toolkit to include LNPs, offering a versatile platform for targeting various genomic sites with high efficiency and specificity.

Source: https://doi.org/10.21203/rs.3.rs-11118113/v1

Collected: November 15, 2026 | Automated Research System (AI)

#03 X-Editor (XE): Engineering Cas12e for High-Potency In Vivo Editing

Published November 12, 2026 bioRxiv USA



OVERVIEW

Researchers have developed the X-Editor (XE), a compact nuclease platform derived from Cas12e that exhibits over 100-fold higher editing activity in human cells than its predecessor. Tested in nonhuman primate livers via lipid nanoparticles, XE achieved greater editing at lower doses than comparable Cas9-based therapies currently in clinical testing. This advancement enables high-potency genome editing with stringent specificity, reducing off-target risks for genetic medicines.

IN DEPTH

Key Findings

The X-Editor (XE) demonstrates superior in vivo activity and exceptional genomic specificity compared to existing CRISPR systems. In tests using nonhuman primate livers, XE mRNA delivered via lipid nanoparticles (LNP) achieved higher editing efficiency at lower doses than preclinical data from Cas9-based therapies currently in clinical trials. Furthermore, full specificity assessments in primary human hepatocytes showed no detected off-target editing at doses tenfold above the on-target effective concentration (EC90).

Technical Details

The XE platform was created through iterative molecular engineering of the Cas12e protein and its guide RNA. The development process involved:

- Screening tens of thousands of protein variants and guide designs.
- Iterative testing and combination of beneficial mutations to increase potency.
- The use of cryo-electron microscopy to identify the novel inter- and intramolecular interactions that drive the enhanced function.

These optimizations resulted in an enzyme with more than 100-fold higher editing activity in human cells compared to the original system.

Background & Context

While CRISPR-based modifications offer potential for one-time curative treatments, existing microbial nucleases like Cas9 evolved for antiviral defense rather than precision editing in human cells. This creates a challenge for in vivo delivery in large animals, where increasing potency at low doses is required to avoid unintended genomic modifications. The XE platform addresses these limitations by providing a naturally compact system suitable for delivery via either adeno-associated virus (AAV) or lipid nanoparticle (LNP) strategies.

Significance & Outlook

The engineering of the X-Editor establishes that high potency and stringent specificity can be jointly optimized in a compact CRISPR system. By allowing for lower dosing and greatly reducing off-target risks, this platform provides a new foundation for the development of advanced genetic medicines.

Source: https://doi.org/10.64898/2026.11.10.765514

Collected: November 15, 2026 | Automated Research System (AI)

#04 Durvalumab plus EV: FDA approval for cisplatin-ineligible MIBC

Published November 13, 2026 The American Journal of Managed Care USA



OVERVIEW

The FDA has approved a perioperative regimen of durvalumab and enfortumab vedotin (EV) for adult patients with muscle-invasive bladder cancer (MIBC) ineligible for cisplatin. The combination reduced the risk of death by 42% and the risk of recurrence, progression, failure to undergo surgery, or death by 49% compared to surgery alone. This provides a new standard of care for a patient population that previously had poor prognoses with radical cystectomy alone.

IN DEPTH

Key Findings

The FDA approved the combination of durvalumab (Imfinzi) and enfortumab vedotin (EV; Padcev) for the treatment of adult patients with muscle-invasive bladder cancer (MIBC) who are ineligible for or have refused cisplatin-based chemotherapy. Based on the phase 3 VOLGA trial, the regimen demonstrated a 24-month event-free survival (EFS) of 63.5% compared to 45.1% for surgery alone (HR 0.51). The 24-month overall survival (OS) was 78.4% versus 69.4% (HR 0.58), representing a 42% reduction in the risk of death.

Technical Details

The approved perioperative regimen consists of three 21-day cycles of durvalumab (1500 mg) plus EV (1.25 mg/kg) administered before bladder removal, followed by radical cystectomy and nine cycles of adjuvant durvalumab every four weeks. Pathologic complete response was achieved in 45.1% of patients in the durvalumab-EV arm, compared to 9.6% in the surgery-only arm. Grade ≥3 adverse events occurred in 71.1% of the durvalumab-EV group versus 50.2% in the control group, with notable EV-related events including skin reactions (48.7%) and neuropathy (17.5%).

A triplet arm adding tremelimumab improved EFS (24-month EFS 60.1%; HR 0.61) but did not improve OS and increased toxicity and discontinuations.

Background & Context

Approximately 1 in 4 bladder cancer patients have muscle-invasive disease, and up to half are cisplatin-ineligible due to comorbidities or impaired kidney function. While the NIAGARA trial established perioperative durvalumab plus cisplatin for eligible patients, and other regimens combine EV with pembrolizumab both before and after surgery, the VOLGA trial specifically tested a regimen that limits the antibody-drug conjugate (EV) to the pre-surgical phase.

Significance & Outlook

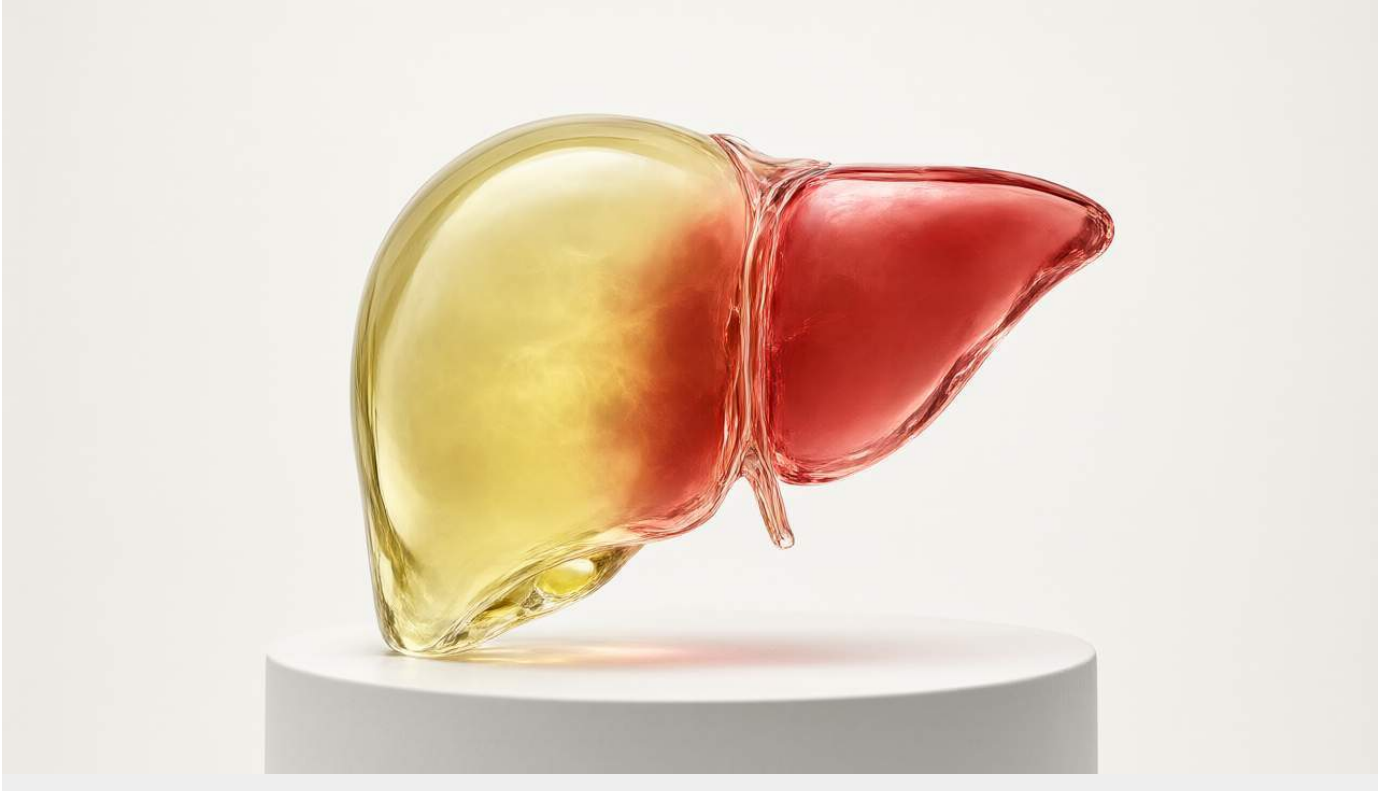
This approval introduces the first perioperative regimen where EV is administered only before surgery. The data suggests that concentrating EV before the stress of surgery, while maintaining immunotherapy on both sides of the cystectomy, offers a manageable safety profile and substantial neoadjuvant cytoreduction. Cystectomy rates were higher in the durvalumab-EV group (85.0% vs 78.6%), with only 0.9% of cancellations driven by adverse events.

Source: https://www.ajmc.com/view/durvalumab-plus-enfortumab-vedotin-before-surgery-cuts-risk-of-death-42-in-cisplatin-ineligible-mibc

Collected: November 15, 2026 | Automated Research System (AI)

#05 CIDEB siRNA: Regeneron's MASLD liver fat reduction trial results

Published November 08, 2026　FT.com（GlobeNewswire / Regeneron Pharmaceuticals）USA



OVERVIEW

A single subcutaneous dose of CIDEB siRNA reduced liver fat by 58-80% and improved liver injury markers in MASLD patients through week 36. The trial demonstrated that 62% of recipients achieved normalized liver fat levels, suggesting a potential for twice-yearly dosing.

IN DEPTH

Key Findings

In a first-in-human trial, a single subcutaneous administration of CIDEB siRNA resulted in rapid and durable reductions in liver fat, with decreases of 58-80% observed at week 36. These results were sustained from an initial reduction of 49-72% at week 6, as measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF). In contrast, the placebo group showed a mean decrease of 2.9% at week 36. Notably, 62% of CIDEB siRNA recipients achieved normalized liver fat (defined as under 5% by MRI-PDFF), while 93% saw reductions of ≥30%.

Technical Details

The Phase 1/2 trial evaluated four dose levels of CIDEB siRNA (n=30 per group) against a placebo (n=10) in adults with metabolic dysfunction-associated steatotic liver disease (MASLD). CIDEB siRNA is a first-in-class, liver-targeted small interfering RNA designed to mimic protective effects of rare CIDEB gene mutations discovered by the Regeneron Genetics Center. Beyond fat reduction, the trial observed sustained improvements in liver injury markers through week 36, including reductions in mean alanine aminotransferase (ALT) and directionally similar changes in aspartate aminotransferase (AST) levels.

Background & Context

MASLD ranges from simple fatty liver to metabolic dysfunction-associated steatohepatitis (MASH), a progressive fibrotic disease affecting approximately 13 million U.S. adults. MASH is characterized by inflammation and cell damage that can lead to cirrhosis or liver cancer. The source notes that previously approved MASH therapies have reached mean liver fat reductions of 47-57% at approximately one year.

Significance & Outlook

The safety profile showed adverse events were generally similar between the siRNA and placebo groups, with most being mild or moderate. No nausea or vomiting was reported, addressing a known limitation of other therapies. One severe event of hyperglycemia occurred but was attributed to adult-onset Type 1 diabetes rather than the study drug. Regeneron is currently recruiting for Phase 2a, Phase 2b, and Phase 3 trials to evaluate longer-term safety and histologic outcomes.

Source: https://markets.ft.com/data/announce/full?dockey=1330-9872883en-3MNI6QMM7DHVQKKI3GI5AB6UVP

#06 Codexis ECO Synthesis: 100g Scale Performance and siRNA Specs

Published November 09, 2026 Markets Insider（GlobeNewswire / Codexis） USA



OVERVIEW

Codexis presented data at TIDES Europe 2026 showing its ECO Synthesis platform achieves over 90% product quality at a 100-gram scale while nearly halving cycle time. The platform also demonstrated a 3- to 4-fold increase in potency in human hepatocyte in vitro models compared to traditional chemical synthesis. These results indicate a scalable, enzymatic alternative to solid phase organic synthesis for RNAi therapeutics.

IN DEPTH

Key Findings

Codexis has demonstrated the scalability and quality of its ECO Synthesis Manufacturing Platform at a 100-gram scale. Data presented at TIDES Europe 2026 show that the platform achieves product quality exceeding 90% and has nearly halved cycle times. This level of performance and quality was maintained consistently across three orders of magnitude in scale.

Technical Details

The ECO Synthesis platform enables precise control over siRNA stereochemistry and the efficient incorporation of tissue-targeting moieties. In an ongoing structure-activity relationship (SAR) study, Codexis compared material produced via ECO Synthesis against identical siRNA synthesized using traditional chemical methods. The results showed a 3- to 4-fold increase in potency within human hepatocyte in vitro models for the enzymatically synthesized material with defined phosphorothioate stereochemistry.

Background and Context

ECO Synthesis is an aqueous enzymatic process designed as a scalable alternative to traditional solid phase organic synthesis for oligonucleotide manufacturing. Codexis is currently applying this technology to the RNAi therapeutics market. The company's proprietary enzymes are intended to provide several operational advantages over traditional methods, including:

- Higher yields and increased purity.
- Reduced energy usage and waste generation.
- Stereoisomer control of siRNA.
- Lower capital requirements for manufacturing capacity.

Significance and Outlook

The ability to maintain quality at the 100-gram scale, combined with the capacity for stereochemical control and targeted delivery, moves the ECO Synthesis platform toward industrial adoption readiness. By enabling molecular precision and improved manufacturing efficiency, the platform provides tools to optimize the design and performance of next-generation RNA therapeutics. Codexis continues to refine the process to increase productivity as it advances toward full industrialization.

Source: https://markets.businessinsider.com/news/stocks/codexis-advances-eco-synthesis-toward-adoption-readiness-with-quality-at-scale-and-expanded-sirna-manufacturing-capabilities-1036736462

Collected: November 15, 2026 | Automated Research System (AI)

#07 PS-10 Molecular Glue: BTK Degradation and PPI Interface Specs

Published November 06, 2026 Research Square



OVERVIEW

Researchers have discovered PS-10, the first molecular glue targeting Bruton's tyrosine kinase (BTK), which achieves a DC 50 in the single-digit nanomolar range and a D max exceeding 95%. The molecule utilizes a plastic protein-protein interaction (PPI) interface rather than rigid degrons, providing a new blueprint for rational molecular glue design.

IN DEPTH

Key Findings

The study identifies PS-10 as the first BTK-targeting molecular glue capable of efficient protein degradation. Despite exhibiting negligible binary binding affinity for the kinase itself, PS-10 achieves a D max exceeding 95% and a DC 50 in the single-digit nanomolar range.

Technical Details

Cryo-EM and computational modeling indicate that PS-10 induces a PPI interface between the E3 ligase CRBN and BTK. This interaction is stabilized by an induced-fit rotation of the BTK N-lobe, creating extensive PPIs that differ from previously documented CRBN-substrate complexes. Global proteomics and mutational mapping further reveal that this degradation mechanism is not exclusive to BTK; it extends to other kinases, including CSK, AURKA, LIMK1, and TEC, relying on a diverse set of PPI residues.

Background & Context

Targeted protein degradation (TPD) is a therapeutic strategy that utilizes cellular proteolytic systems to eliminate disease-associated proteins. Traditionally, the field has relied on specific degrader classes, often requiring rigid, pre-existing degrons to facilitate the interaction between the E3 ligase and the target protein.

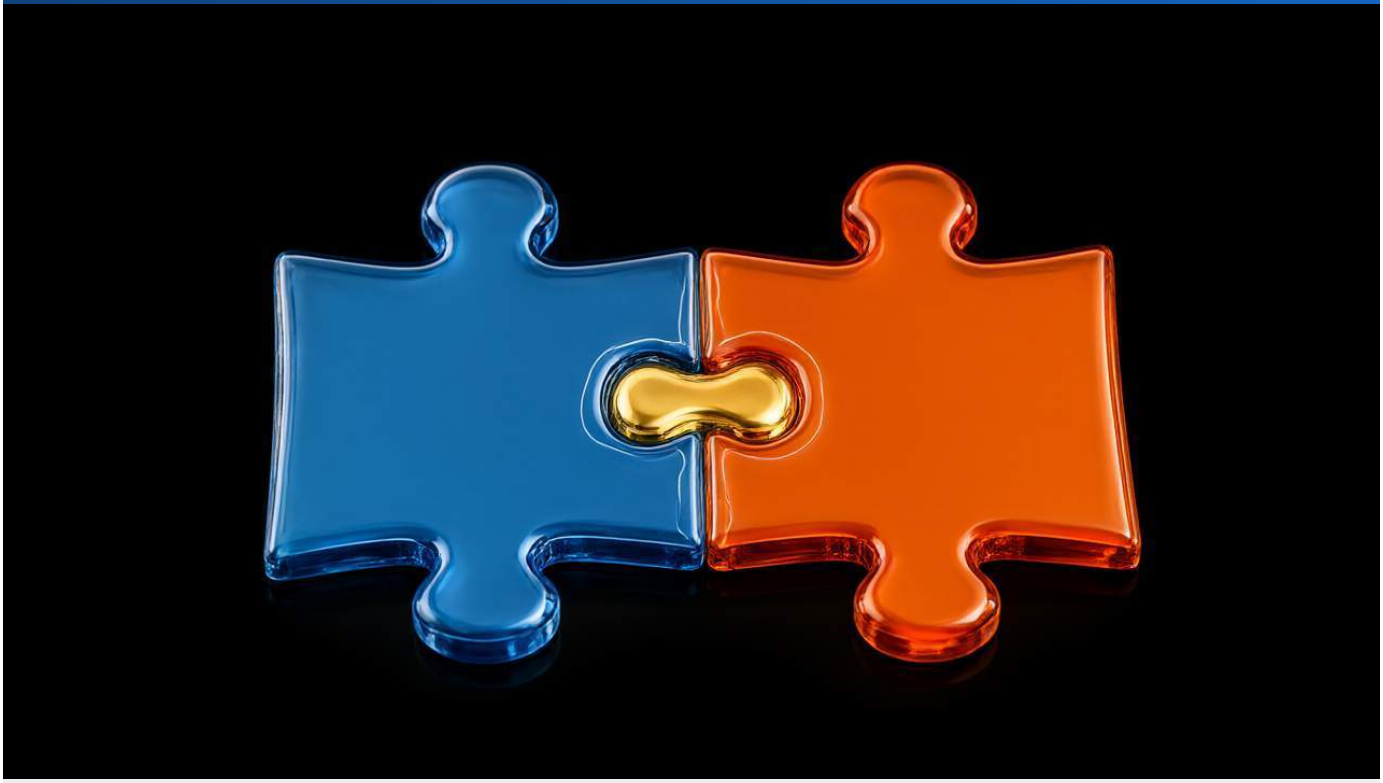
Significance & Outlook

The discovery of PS-10 demonstrates significant structural plasticity in E3-neosubstrate PPIs, proving that productive interactions can be achieved via distinct structural trajectories. The findings suggest that rigid degrons are not mandatory for effective degradation. Instead, the presence of even a weak target binder can be leveraged to exploit plastic PPI interfaces to maximize cooperativity. This shift in understanding establishes a generalizable blueprint for the rational design of future molecular glues.

Source: https://doi.org/10.21203/rs.3.rs-11296825/v1

#08 GluePlex: Predicting CRBN-Neosubstrate Ternary Complex Structures

Published November 11, 2026 Research Square



OVERVIEW

GluePlex improves the prediction of novel cereblon (CRBN) ternary complexes by combining restrained protein–protein docking with template-guided Boltz-2 co-folding. In tests on novel pairs, it increased the number of acceptable poses to 23 of 39 runs with a median DockQ of 0.43, compared to 12 of 39 runs and a median DockQ of 0.01 for plain Boltz-2. This approach moves molecular-glue degrader design toward a more rational, rather than empirical, process.

IN DEPTH

Key Findings

GluePlex significantly enhances the accuracy of predicting molecular-glue induced CRBN-neosubstrate ternary complex structures. When tested on 13 novel pairs, GluePlex achieved a median DockQ (protein-interface accuracy score) of 0.43, with 19 rank-1 successes among 23 successful runs out of 39. In contrast, plain Boltz-2 co-folding produced acceptable poses in only 12 of 39 runs, with a median DockQ of 0.01.

Technical Details

The GluePlex pipeline integrates three primary components:

- Ligand-free, restrained protein–protein docking.
- Two passes of template-guided Boltz-2 co-folding.
- The use of multiple conformers.

Ablation analysis indicated that the majority of the performance gains were attributed to the docking and template transfer components. However, ligand placement accuracy remains a challenge. While the CRBN-binding warhead showed a median root-mean-square deviation (RMSD) of 0.7 Å, the distal moiety had a median RMSD of 2.8 Å, remaining inaccurate even when the protein interface was correctly predicted.

Background & Context

Molecular glue degraders function through a single induced geometry. Predicting this geometry in silico is essential for transitioning degrader design from empirical methods to rational design. To evaluate performance, the researchers assembled 52 CRBN target–compound pairs with published ternary structures, stratifying them by their exposure to the training set to specifically test performance on structurally novel neosubstrates.

Significance & Outlook

Across various configurations and ligand truncations, an acceptable pose was recovered for 12 of 13 novel families, while the final family could be recovered using plain co-folding. This indicates that while no single configuration solves all cases, GluePlex broadly improves prediction capabilities. The primary remaining limitations for the technology are model ranking and the precise placement of the distal ligand.

Source: https://doi.org/10.21203/rs.3.rs-11580478/v1

Collected: November 15, 2026 | Automated Research System (AI)

#09 ImvivaBio CTA313: Dual CD19/BCMA CAR-T Data for Lupus (2026)

Published November 11, 2026　Yahoo Finance（ImvivaBio のプレスリリース）　USA



OVERVIEW

ImvivaBio presented 12-month follow-up data for CTA313, an allogeneic dual-targeted CD19/BCMA CAR-T therapy for systemic lupus erythematosus (SLE) and lupus nephritis (LN). The therapy achieved an 88% DORIS remission rate at Month 12 in refractory SLE patients and demonstrated a superior immune reset compared to single-target CD19 approaches. These results support the transition to a global Phase 1b ALLNEW basket study.

IN DEPTH

Key Findings

CTA313 demonstrated durable remission and immune reconstitution in patients with refractory SLE. In a pooled analysis of 14 heavily pretreated patients with minimal renal involvement, the Definition of Remission in SLE (DORIS) remission rate reached 73% at Month 6 and 88% (7/8 patients) at Month 12. Furthermore, 92.9% of these patients were off immunosuppressants at the data cutoff, and 92% of evaluable patients were taking glucocorticoids at 5 mg/day or less by Month 6.

Technical Details

CTA313 is an "off-the-shelf" allogeneic CAR-T therapy targeting both CD19 and B-cell maturation antigen (BCMA). This dual-targeting approach aims to eliminate both autoreactive B-cell precursors and plasma-cell reservoirs to prevent relapse. Technical data indicates:

- **B-cell Dynamics:** Median B cells dropped from 52.2 to 0 cells/μL by Day 7, with reconstitution around Day 42 consisting of more than 95% naive B cells.
- **Biomarkers:** Anti-dsDNA antibodies became undetectable by Month 3 and remained so for up to one year; complement component C3 rose from 0.65 to 1.34 g/L by Day 28.
- **Comparative Efficacy:** In SLE with minimal renal involvement, the dual-target approach achieved a 12-month DORIS remission rate of 80%, compared to 20% for single-target CD19 CAR-T (n=17 for single vs n=27 for dual).
- **Safety:** Cytokine release syndrome (CRS) occurred in 35.7% of patients (all Grade 1). Grade 3 or higher adverse events included neutropenia (71.4%), thrombocytopenia (21.4%), and infections (21.4%). No neurotoxicity or graft-versus-host disease (GvHD) was observed.

Background and Context

Current standard-of-care for SLE and LN relies on broad immunosuppression, which often results in incomplete responses and recurrent flares. ImvivaBio's approach utilizes an allogeneic "immune reset" mechanism, where single-cell analysis showed no overlap between pretreatment autoreactive clones and newly formed clones.

Significance and Outlook

The data suggests that dual CD19/BCMA targeting provides deeper B-cell eradication and superior remission outcomes than single-target therapies. These findings inform the design of the upcoming global Phase 1b ALLNEW basket study.

Source: https://finance.yahoo.com/healthcare/articles/imvivabio-presents-longer-term-data-130000771.html

Collected: November 15, 2026 | Automated Research System (AI)

#10 Asundexian: FDA Approval and OCEANIC-STROKE Trial Results

Published November 09, 2026 NeurologyLive USA



OVERVIEW

The FDA has approved asundexian (Sunharbo), the first factor XIa inhibitor for the secondary prevention of noncardioembolic ischemic stroke and high-risk TIA. In phase 3 trials, a 50 mg daily dose combined with antiplatelet therapy reduced ischemic stroke incidence to 6.2% compared to 8.4% for placebo without a significant increase in major bleeding.

IN DEPTH

Key Findings

The FDA has approved Bayer's asundexian (marketed as Sunharbo), an oral factor XIa (FXIa) inhibitor, to reduce the risk of recurrent stroke in adults following a noncardioembolic ischemic stroke or high-risk transient ischemic attack (TIA). The approval is based on the phase 3 OCEANIC-STROKE trial, which demonstrated that asundexian 50 mg once daily, used in combination with antiplatelet therapy, significantly reduced the risk of ischemic stroke by 26% over a median treatment period of 14.2 months.

Technical Details

The double-blind OCEANIC-STROKE trial enrolled 12,327 patients (asundexian, n = 6162; placebo, n = 6165) randomized within 72 hours of a qualifying event. Eligible patients had an NIHSS score of 15 or less and presented with at least one of the following: a nonlacunar infarct on imaging, a history of atherosclerosis, or atherosclerotic plaque on cerebrovascular imaging.

- **Primary Efficacy:** Ischemic stroke occurred in 6.2% of the asundexian group vs 8.4% in the placebo group (HR 0.74; P <.001). Ischemic or hemorrhagic stroke occurred in 6.6% vs 8.8% (HR 0.74; P <.001).
- **Composite Outcomes:** Cardiovascular death, myocardial infarction, or stroke occurred in 9.2% vs 11.1% (HR 0.83; P <.001). All-cause death, MI, or stroke occurred in 10.5% vs 12.3% (HR 0.85; P = .003).
- **Safety:** ISTH-defined major bleeding occurred in 1.9% of asundexian patients vs 1.7% for placebo (HR 1.10; P = .46). Serious adverse events were reported in 19.2% vs 19.5%.

Background & Context

Non-cardioembolic ischemic strokes represent approximately 45% of the 12 million global annual strokes, with roughly 1 in 10 patients experiencing recurrence within one year despite guideline-recommended therapy. The 50-mg dose used in this trial was informed by the phase 2b PACIFIC-STROKE trial, which showed a signal for fewer symptomatic strokes, particularly in patients with atherosclerosis.

Significance & Outlook

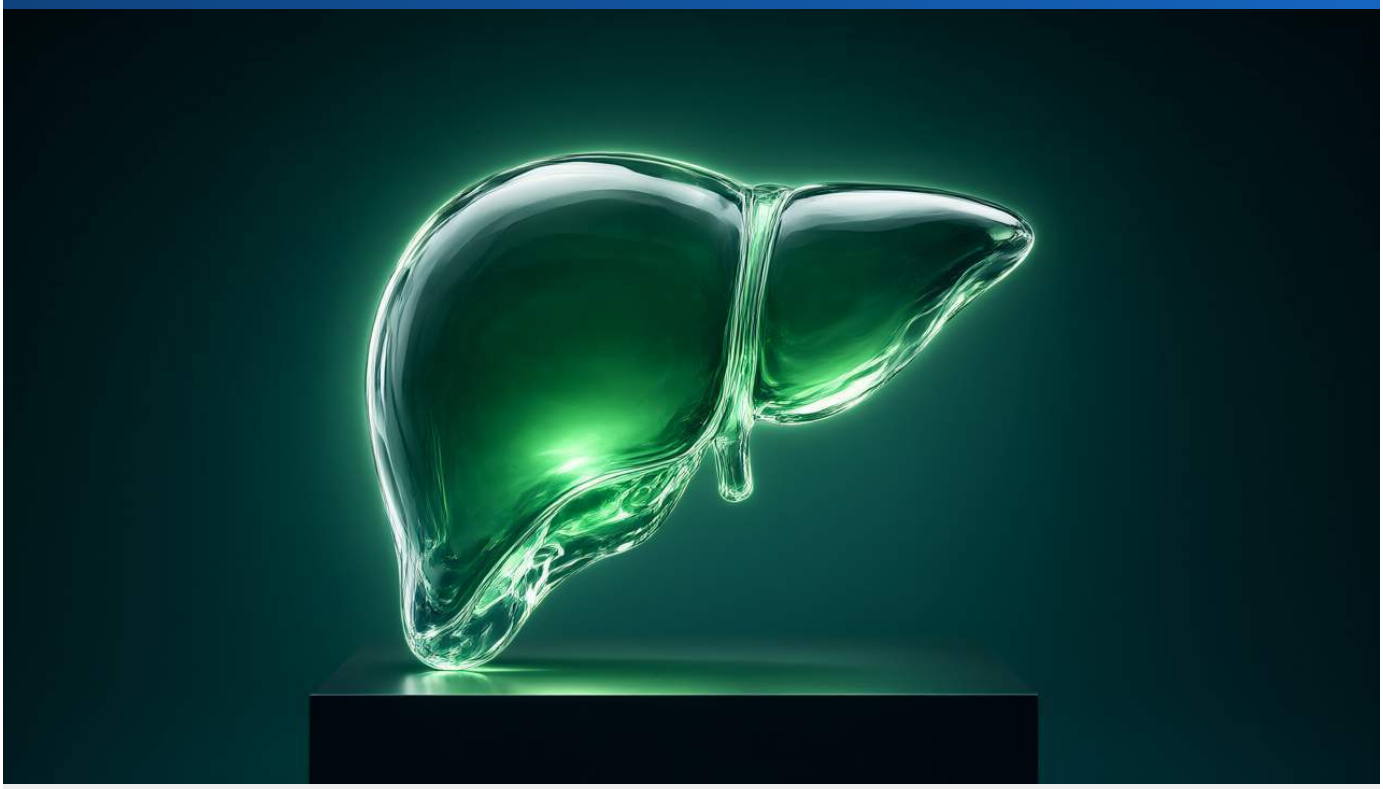
Asundexian is the first FXIa inhibitor approved for secondary stroke prevention. Its use is limited to noncardioembolic stroke/high-risk TIA populations; it is not approved for atrial fibrillation and is not recommended for patients with moderate or severe hepatic impairment. Clinical labeling advises avoiding combined P-gp/strong CYP3A4 inducers and withholding the drug for at least 24 hours before elective procedures or after thrombolysis.

Source: https://www.neurologylive.com/view/fda-approves-asundexian-treatment-secondary-stroke-prevention

Collected: November 15, 2026 | Automated Research System (AI)

#11 Vir Biotechnology: Elebsiran and Tobevibart Phase 2 SOLSTICE Data

Published November 08, 2026　Business Wire（AOL掲載）　USA



OVERVIEW

Combination therapy with elebsiran and tobevibart achieved 100% undetectable viremia in patients completing 96 weeks of treatment for chronic hepatitis delta (CHD). Exploratory data suggests curative potential, with all ten patients who discontinued treatment achieving SVR12. These results support a planned global regulatory filing for the U.S. FDA in mid-2027.

IN DEPTH

Key Findings

In the Phase 2 SOLSTICE trial, 100% (28/28) of patients who completed 96 weeks of monthly subcutaneous administration of elebsiran and tobevibart reached undetectable viremia. This deep virologic response was accompanied by improvements in liver health; 89% (24/27) of patients with paired liver stiffness measurements showed improved or stable liver stiffness at Week 96. The regimen was generally well-tolerated, with mild to moderate adverse events and no serious adverse events or study drug-related discontinuations.

Technical Details on Finite Treatment

Exploratory analyses evaluated the durability of viral suppression following treatment discontinuation for patients who maintained undetectable virus for at least 96 weeks. Ten patients, including seven with cirrhosis, discontinued treatment. Results showed:

- 100% (10/10) of patients achieved SVR12.
- 7 patients achieved SVR24 and 1 patient achieved SVR48.
- No viral rebound or ALT flares were observed, and all 10 patients maintained stable ALT levels.

Background and Context

The combination is currently being evaluated under the ECLIPSE registrational program, which consists of three randomized, controlled trials. Vir Biotechnology reported that the pivotal Phase 3 ECLIPSE 1 trial met all study endpoints. Other trials include ECLIPSE 2, focusing on patients who failed bulevirtide therapy, and ECLIPSE 3, a head-to-head trial against bulevirtide in naïve patients.

Significance and Outlook

The potential for a finite treatment approach may shift the management of CHD from chronic suppression to a potential cure. The U.S. FDA has granted the combination Breakthrough Therapy and Fast Track designations, while the EMA has provided Priority Medicines (PRIME) and orphan drug designations. Commercialization in Europe, Australia, and New Zealand will be handled by Norgine under a December 2025 licensing agreement. A comprehensive global regulatory filing is planned for submission to the U.S. FDA in mid-2027.

[[END]]

Source: https://www.aol.com/articles/vir-biotechnology-announces-expanded-phase-214500000.html

Collected: November 15, 2026 | Automated Research System (AI)