WEEKLY INTELLIGENCE BRIEF

Week in Review

JULY 11, 2026

A high-profile **Phase 3 ATTR-CM failure**, accelerating **China dealmaking**, and **two FDA approvals** reshape competitive dynamics across oncology, rare disease, and neuroscience.

01 SECTION

Regulatory & Approvals

Sarclisa becomes the first cancer drug via on-body injector

FDA cleared subcutaneous **Sarclisa** (isatuximab) on July 10, narrowing the convenience gap with J&J's anti-CD38 leader Darzalex.

Sanofi

Padcev + Keytruda expands in bladder cancer

FDA (Jul 10) cleared the **Astellas/Pfizer–Merck** combo for muscle-invasive disease regardless of cisplatin eligibility — the first platinum-free regimen.

FDA

Proposed rule to modernize manufacturing registration

FDA would register **hub-and-spoke** distributed networks as a single establishment; multi-site CDMOs stand to benefit if finalized.

FDA

FDA pauses public release of rejection letters

A citizen petition halted publication of **Complete Response Letters** over confidentiality concerns — issuance to sponsors is unaffected.

PharmExec

02 SECTION

Clinical Data

Ipsen's Dysport wins both migraine types

E-BEOND and C-BEOND Phase 3 trials hit endpoints — the **first botulinum toxin** to work in episodic migraine and in both subtypes, unlike Botox.

NeurologyLive

First Phase 3 survival win for a B7-H3 ADC

GSK / Hansoh's Ris-Rez (ARTEMIS-008) beat topotecan on overall survival in small-cell lung cancer in China.

BioPharma Dive

Compass psilocybin durability confirmed

26-week COMP006 data holds; **COMP360**'s rolling FDA NDA is underway and on track for completion in Q4 2026.

PharmaTimes

Prime Medicine wins Beam arbitration

Tribunal cleared **PM647** (alpha-1 antitrypsin prime editing); an IND/CTA filing is planned for Q3 2026.

STAT

03 SECTION

Deals & Partnerships

GSK ends its Alector neuroscience alliance

180-day notice (Jul 6; effective Jan 2, 2027) unwinds a deal worth up to **$2.2B** after dementia and Alzheimer's setbacks.

BioPharma Dive

Scipher × Chemomab all-stock merger

Gives Scipher a Nasdaq listing and redirects **nebokitug** (anti-CCL24) into an AI-guided Phase 2 in rheumatoid arthritis.

Fierce Biotech

Halma buys pathology-automation firm Dreampath

€154M upfront plus up to €121M in milestones (up to €275M) expands its lab-workflow portfolio.

Pharmafile

ARPA-H commits up to $160M to bespoke gene editing

New **THRIVE** program backs seven teams building personalized gene-editing therapies for rare diseases over five years.

Endpoints

04 SECTION

Business & Finance

Dr. Reddy's pauses generic semaglutide supply

An **API quality issue** (Jul 9) removes a major generic source, temporarily aiding rival generics and Novo Nordisk's Ozempic/Wegovy.

Fierce Pharma

Novartis cuts 322 more New Jersey jobs

A fourth East Hanover round in 2026 reorganizes **field sales, patient support and marketing** for efficiency.

PharmExec

BioNTech "right-sizes" its HER2 ADC launch

CCO Hanekamp frames it as **"building the muscle"** for a higher-priority BMS-partnered bispecific; Enhertu still dominates.

Fierce Pharma

05 SECTION

Competitive Positioning Heatmap

WINNERS THIS WEEK

Alnylam — ATTR-CM field narrows as eplontersen fails its endpoint

Pfizer — Less ATTR-CM competition for tafamidis; Padcev-Keytruda expands

Ipsen — Dual migraine wins open the first neurotoxin episodic opportunity

Prime Medicine — Arbitration win clears its AATD prime-editing program

UNDER PRESSURE

AstraZeneca — Eplontersen ATTR-CM miss; Padcev-Keytruda adds urothelial pressure

Ionis — CARDIO-TTRansform failure removes projected Wainua upside

Dr. Reddy's — API issue forces a generic semaglutide supply halt

Beam Therapeutics — Arbitration loss leaves AATD position on own execution

NEUTRAL BUT PIVOTAL

Compass Pathways — Rolling FDA NDA for COMP360 underway; Q4 2026 target

Alector — Reclaims neuroscience assets post-GSK; financing path unclear

Sanofi — On-body injector tests whether delivery shifts anti-CD38 share

\+ THERE'S MORE IN THE FULL BRIEF

Read the full breakdown

ALSO INSIDE

Read more →

Data Snapshot

The numbers that matter: **140-week** CARDIO-TTRansform endpoint · **$2.2B** GSK–Alector value · **€275M** Halma–Dreampath · **931-day** DCVax-L UK review.

ALSO INSIDE

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What to Watch Next

Forward catalysts: **Compass COMP360** FDA submission · **Ipsen Dysport** filing timeline · fallout from the **Hikma v. Amarin** skinny-label ruling.

FULL WEEKLY INTELLIGENCE BRIEF

Get the complete analysis, sources & competitive framing →

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