VYUHPHARMA

Highlights from the Week of November 10-17, 2025

ORGANON

Organon and Henlius received FDA approval for their biosimilar, POHERDY, as the first interchangeable biosimilar to Roche's Perjeta, for use in HER2-positive breast cancer indications

(FDA, Approval)

amneal

Amneal Pharmaceuticals received FDA approval for IOHEXOL injection, a generic radiographic contrast agent equivalent to Omnipaque, with launch expected in QI 2026

(FDA, Approval)

KURA ONCOLOGY

The FDA granted full approval to Kura and Kyowa Kirin's oral therapy, KOMZIFTI (ziftomenib), for relapsed/refractory NPM1-mutated AML

(FDA, Approval)

Highlights from the Week of November 10-17, 2025

IONIS

The CHMP adopted a positive opinion for Ionis' DAWNZERA (donidalorsen), recommending EU approval for preventing hereditary angioedema (HAE) attacks

(CHMP Opinion)

FONDAZIONE Telethon

The CHMP adopted a positive opinion for Fondazione Telethon's Waskyra, recommending the gene therapy's approval in the European Union for treating Wiskott-Aldrich syndrome (WAS)

(CHMP Opinion)

MARCH BIOSCIENCES

The FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to March Biosciences' CAR-T therapy, MB-105, for relapsed/refractory CD5-positive T-cell lymphoma

(FDA, RMAT Designation)

VYUHPHARMA

Highlights from the Week of November 10-17, 2025

Biogen

The MHRA approved Biogen's LEQEMBI (lecanemab) for a once-monthly IV maintenance dose for early Alzheimer's patients after the initial 18 months of biweekly treatment

(MHRA, Approval)

Shilpa | Innovating for affordable healthcare

Shilpa Medicare's once-weekly OERIS injection successfully completed a Phase 3 trial, demonstrating superior efficacy and safety over conventional ondansetron for preventing CINV

(Results, Phase 3)

COGNISION

Cognision partnered with Kynexis to use its COGNISION EEG/ERP system in a Phase 2 trial of KYN-5356 for schizophrenia, aiming to provide objective neurophysiological markers

(Partnership)