Highlights from the Week of July 07–14, 2025

VYUHPHARMA

(Alzheimers, FDA)

Lilly's KISUNLA gets FDA nod for safer dosing in early Alzheimer's, reducing ARIA-E risk by 41%

(Breakthrough Therapy, FDA)

Transcend Therapeutics has been granted Breakthrough Therapy Designation for TSND- 201 (methylone) for the treatment of PTSD

(Denosumab Biosimilars)

Celltrion launches STOBOCLO and OSENVELT (biosimilars to PROLIA and XGEVA) in the U.S.

(Gene Therapy, Canavan Disease)

Myrtelle launches a commercial-stage manufacturing of MYR-101, its rAAV gene therapy for Canavan disease, in partnership with Charles River and Viralgen

VYUHPHARMA

(Schizophrenia, FDA)

Johnson & Johnson filed an sNDA with the FDA for CAPLYTA (lumateperone), based on long-term Ph3 data showing a 63% reduction in schizophrenia relapse risk in adults

(Leukemia, FDA Approval)

FDA accepts Taiho's sNDA for INQOVI (decitabine and cedazuridine) in combination with venetoclax to treat newly diagnosed AML patients who are ineligible for intensive chemotherapy, with a PDUFA date of February 25, 2026

(Rare Disease, FDA Approval)

FDA approves KalVista's EKTERLY (sebetralstat) for the treatment of hereditary angioedema

(WomensHealth, MHRA Approval)

Bayer's LYNKUET, a hormone-free dual neurokinin-targeted therapy, receives its approval in the UK by the MHRA for the treatment of moderate to severe vasomotor symptoms (hot flashes) associated with menopause

(FDA, NDA, HIV-1)

FDA accepts NDA for Merck's doravirine/islatravir (DOR/ISL) for adults with virologically suppressed HIV-1, with the target action date set for April 28, 2026

(COPD, Mergers And Acquisitions)

Merck plans to acquire Verona Pharma for approximately $10B, adding OHTUVAYRE to its cardio-pulmonary pipeline, acquisition expected to be completed in Q4 2025

(FDA, Rare Disease)

Capricor Therapeutics received a CRL from the FDA for its BLA for Deramiocel for Duchenne muscular dystrophy

(Narcolepsy Type I, Phase 3 Results)

Oveporexton's Ph3 studies met all endpoints, showed symptom improvements and a good safety profile, leading Takeda to accelerate regulatory submissions for a potential narcolepsy type I treatment

(PSVT, FDA)

Milestone Pharmaceuticals confirms FDA acceptance of its CRL response for CARDAMYST™ nasal spray, designed to treat PSVT; FDA sets new PDUFA action date for December 13, 2025