

●▶ **Cycle Pharma**

(FDA, Approval)

FDA approves HARLIKU™ (nitisinone) as the first and only treatment for ultra-rare alkaptonuria; U.S. launch set for July 2025

●▶ **Bayer**

(FDA, Approval)

Bayer submits NDA for gadoquatrane at 0.04 mmol/kg, reducing gadolinium exposure by 60%

●▶ **Sanofi & Regeneron**

(FDA, Approval)

FDA approves Dupixent as the first and only targeted medicine for bullous pemphigoid in adults

●▶ **Sage Therapeutics + Supernus Pharmaceuticals** *(Neuropsychiatry, Acquisition)*

Supernus Pharmaceuticals is set to acquire Sage Therapeutics for up to \$795 million, adding ZURZUVAE to its neuropsychiatry portfolio



●▶ **Eli Lilly + Verve Therapeutics** *(Acquisition, Cardiovascular Health)*

Lilly's acquisition of Verve brings VERVE-102, a potential one-and-done PCSK9 therapy, into its cardiovascular pipeline

●▶ **Madrigal Pharma** *(Liver Fibrosis, CHMP)*

The CHMP recommends resmetirom (REZDIFFRA) for adults with MASH and moderate to advanced fibrosis

●▶ **Ipsen** *(CHMP, Cancer Treatment)*

Ipsen receives positive CHMP opinion for Cabometyx in advanced pNET and epNET following prior therapy

●▶ **Lomond Therapeutics** *(IND, FDA)*

Lomond receives FDA clearance for its IND application of lonitoclax, a selective BCL-2 inhibitor with improved safety over venetoclax



●▶ **CSL**

(FDA, Approval)

FDA approves CSL's Andembry (garadacimab-gxii) as the first prophylactic HAE therapy targeting factor XIIa with once-monthly dosing

●▶ **Partner Therapeutics**

(RadiationSyndrome, CHMP)

The CHMP recommends IMREPLYS (sargramostim) for EU approval as an emergency treatment for radiation-induced bone marrow suppression

●▶ **Bio-Thera**

(CHMP, Biosimilars, Stelara)

Bio-Thera Solutions receives positive CHMP opinion for USYMRO, referencing STELARA in the treatment of plaque psoriasis

●▶ **AbbVie**

(Results, MigrainePrevention, ClinicalTrials)

AbbVie's atogepant/QULIPTA shows superiority to topiramate across all measures in the Phase 3 TEMPLE head-to-head migraine study



► Halozyme*(EC, DrugApproval)*

Halozyme announces EU approval of argenx's VYVGART® subcutaneous with ENHANZE® for chronic inflammatory demyelinating polyneuropathy

► Gilead Sciences*(HIVPrevention, FDA, Approval)*

FDA clears lenacapavir (Yeztugo) for PrEP in adults/adolescents, marking a milestone in long-acting HIV prevention

► Incyte*(FDA, Approval)*

FDA approves MONJUVI (tafasitamab-cxix) in combination with with rituximab and lenalidomide for relapsed or refractory follicular lymphoma

► Senti Bio*(FDA, OrphanDrug)*

FDA grants orphan drug designation to Senti Bio's SENTI-202, the first-in-class off-the-shelf CAR NK therapy for AML

