(FDA, Approval)

VYUHPHARMA

Highlights from the Week of 30th March 2026 - 6th April 2026

Lilly

Eli Lilly receives FDA approval for FOUNDAYO, the first and only non-peptide, oral GLP-1 receptor agonist for chronic weight management

(FDA, Approval)

Biogen

Biogen's SPINRAZA 50 mg/5 mL and 28 mg/5 mL receives FDA approval for the treatment of spinal muscular atrophy

(FDA, Approval)

teva

FDA grants approval to Teva's PONLIMSI, a PROLIA biosimilar, for all indications of the reference product, followed by a review acceptance for its XOLAIR by the FDA and EMA

(FDA, Approval)

Highlights from the Week of 30th March 2026 - 6th April 2026

UCB's KYGEVVI obtains EC approval for the treatment of genetically confirmed thymidine kinase 2 deficiency with symptom onset at or before 12 years

(EU, Approval)

EC provides conditional marketing authorization to Sanofi's REZUROCK for the treatment of chronic graft-vs-host disease in those aged 12 years and older who weigh at least 40 kg

(EU, Approval)

Bayer's KERENDIA receives EC approval for a new indication to treat heart failure in adults with left ventricular ejection fraction ≥40%

(EU, Approval)

VYUHPHARMA

Highlights from the Week of 30th March 2026 - 6th April 2026

Henlius

CHMP grants two positive opinions for Henlius' serplulimab, an anti-PD-1 monoclonal antibody, recommending approval in combination with chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic nsqNSCLC

(CHMP, Positive Opinion)

zymeworks
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ZW191, a FRα targeting antibody-drug conjugate of Zymeworks, secures Fast Track designation from the FDA for the treatment of advanced or metastatic platinum-resistant ovarian cancer

(FDA, Fast Track)

Abbisko

EMA grants Orphan Drug designation to Abbisko's irpagratinib, an FGFR4 inhibitor for the treatment of hepatocellular carcinoma

(EMA, Orphan Drug)

VYUHPHARMA

Highlights from the Week of 30th March 2026 - 6th April 2026

Oculis

Oculis' neuroprotective peptoid candidate Privosegtor gains Priority Medicines designation from the EMA for the treatment of optic neuritis

(EU, PRIME)

VIRIDIAN

Viridian Therapeutics' Phase 3 REVEAL-1 trial evaluating elegrobart Q4W and Q8W met its primary and all key secondary endpoints in active thyroid eye disease when compared with placebo

(Phase 3, Results)

Gan & Lee

Gan & Lee Pharmaceuticals' once-weekly GZR4 injection met the primary endpoints in the SUPER-1 and SUPER-2 Phase 3 trials, demonstrating superior efficacy in reducing HbAlc

(Phase 3, Results)

VYUHPHARMA

Highlights from the Week of 30th March 2026 - 6th April 2026

AstraZeneca

AstraZeneca's EMERALD-3 Phase 3 trial shows that IMFINZI plus IMJUDO, lenvatinib and TACE significantly improved progression-free survival in unresectable liver cancer compared to TACE alone

(Phase 3, Results)

AstraZeneca

AstraZeneca's global Phase 3 program demonstrated positive results for efzimfotase alfa with an acceptable safety profile across the MULBERRY, CHESTNUT and HICKORY trials

(Phase 3, Results)

MERCK

Merck announces the third positive Phase 3 result, CORALreef, an AddOn active comparator study for enlicitide, resulting in greater LDL-C goal attainment with enlicitide than the secondary endpoint comparators

(Phase 3, Results)

Highlights from the Week of 30th March 2026 - 6th April 2026

NJ Bio and Aji Bio-Pharma announce a research collaboration to expand access to AJICAP, a site-specific conjugation platform, thereby supporting the development of NJ Bio's next-generation antibody-drug conjugates and other targeted therapeutics

(Collaboration)

Shionogi acquires RADICAVA, including intellectual property rights and sales rights in major countries and regions from Tanabe Pharma Corporation, adding to its ongoing strategic investments in rare diseases

(Acquisition)