Highlights from the Week of 29th June 2026 - 06th July 2026

VYUHPHARMA

(FDA, Approval)

FDA approves Vertex's CASGEVY for expanded use to treat people aged 2 years and older with either SCD with recurrent VOCs or transfusion-dependent beta thalassemia

(FDA, Approval)

Orca Bio gets FDA approval of ORCA-T for use in chronic GVHD-free survival in the treatment of adults with hematological malignancies

(EU, Approval)

EC approves Novartis' ITVISMA for the treatment of children aged two years and older, teens and adults with 5q SMA with a bi-allelic mutation in the SMN 1 gene

(FDA, Priority Review)

FDA provides priority review to Roche's sBLA for ENSPRYNG as a subcutaneous therapy for the treatment of TED

VYUHPHARMA

(FDA, RPDD)

NanoViricides' NV-387 for measles receives Rare Pediatric Disease Drug designation from the FDA, enabling the issuance of a Priority Review Voucher

(CHMP, Positive Opinion)

CHMP recommends positive opinion for Amneal's HOPLEDO to treat adults with Parkinson's disease and moderate to severe motor fluctuations

(CHMP, Positive Opinion)

CHMP adopts positive opinion recommending approval for AbbVie's RINVOQ to treat adults and adolescents with NSV

(Collaboration)

EirGenix collaborates with Sandoz AG to commercialize its biosimilar EG1206A for an upfront payment of USD 152M, with profit-share entitlement in the licensed territory

(Phase 3, Results)

AbbVie's Phase 3 EPCORE DLBCL-4 trial evaluating epcoritamab combination compared to R-GemOx in adults with relapsed or refractory DLBCL demonstrates clinically meaningful improvement in PFS with reducing the risk of disease progression and death by 60%

(Phase 3, Results)

Genentech's Phase 3 study evaluating divarasib against sotorasib or adagrasib in NSCLC met its primary and key secondary endpoints, achieving clinically meaningful improvements in PFS and OS with a consistent safety profile

(Phase 3, Results)

Viatris' Phase 3 trial evaluating NEFECON in Japanese adults with IgAN met its primary and secondary endpoints, demonstrating a 33.75% UPCR reduction at 9 months compared to baseline

(Phase 3, Results)

Sanofi's Phase 3 Baby-COMET trial investigating NEXVIAZYME met its primary and all secondary endpoints at 12 and 18 months of age in treatment-naïve pediatric participants with IOPD