Highlights from the Week of 18th August, 2025 - 25th August, 2025

VYUHPHARMA

(FDA, Approval)

FDA approves Ionis's DAWNZERA as first RNA-targeted hereditary angioedema therapy; it shows significant and sustained attack rate reduction, with dosing every 4 or 8 weeks

(EC, Approval)

EU grants marketing authorization to SpringWorks Therapeutics-Merck KGaA's OGSIVEO for adult desmoid tumours

(EC, Approval)

Madrigal receives European Commission approval for REZDIFFRA for MASH with moderate to advanced liver fibrosis

(EC, Approval)

Advanz Pharma and Alvotech gain European Commission approval for MYNZEPLI biosimilar to Eylea after confirmatory clinical equivalence

(FDA, CRL)

PTC Therapeutics receives FDA complete response letter for vatiquinone in Friedreich's ataxia

(FDA, NDA, Resubmission)

FDA accepts NDA resubmission for Stealth's elamipretide to treat Barth syndrome, with a potential approval date as early as September 2025

(FDA, Breakthrough Therapy Designation)

SystImmune and Bristol Myers Squibb receive FDA breakthrough therapy designation for izalontamab brengitecan in EGFR-mutated NSCLC

(FDA, Breakthrough Therapy Designation)

Antengene's ATG-022 receives Breakthrough Therapy designation for treating gastric and gastroesophageal junction adenocarcinoma

(FDA, Fast Track Designation)

Aldeyra Therapeutics receives FDA Fast Track designation for ADX-2191 (methotrexate intravitreal injection) for retinitis pigmentosa

(FDA, Orphan Drug Designation)

Soligenix receives FDA orphan drug designation for dusquetide (SGX945) for treatment of Behçet's disease

(Biosimilars, Collaboration)

Bio-Thera and STADA extend biosimilars alliance to tocilizumab, a key treatment for inflammatory disorders, for European markets

(Phase 3, Results)

Akeso's gumokimab meets primary and key secondary endpoints in Ph3 ankylosing spondylitis trial, while manfidokimab improves skin lesions and pruritus in atopic dermatitis