



(FDA, Approval)
Mirum obtains FDA approval for ATEBRIOZ tablets to reduce the volume of HO in those aged 12 years and older with FOP



(FDA, Approval)
Lantheus gets final approval from FDA for BRAVNETSA to treat adults with somatostatin receptor-positive GEP-NETs, including foregut, midgut, and hindgut neuroendocrine tumors



(FDA, Approval)
Eli Lilly gains FDA approval for ONSWIK, indicated along with diet and exercise, to control high blood sugar in adults with type 2 diabetes



(FDA, Approval)
FDA grants approval to Eleva Therapeutics' LYRFIGTU as a treatment option for CCA with FGFR2 fusion or other rearrangement





(FDA, Approval)

FDA gives approval to Eisai's dual oral regimen, WELIREG plus LENVIMA to treat adults with advanced ccRCC following treatment with a PD-I or PD-LI inhibitor



(FDA, Approval)

FDA approves Merck's label update on WINREVAIR for 45mg and 60mg injection to treat adults with PAH



(FDA, Approval)

FDA provides label expansion approval to Eli Lilly's OLUMIANT once-daily pill to treat those aged 12 years and older with severe alopecia areata



(EU, Approval)

AstraZeneca's TRIxEO Aerosphere receives EC approval as a maintenance treatment for asthma in patients 12 years of age and older



(EU, Approval)



AbbVie obtains EC approval for RINVOQ to treat active polyarticular juvenile idiopathic arthritis in those aged two years and older who respond inadequately to DMARDs

(EU, Approval)



EC grants marketing authorization to Shionogi's ZOKOVEA for PEP of COVID-19 in adults and adolescents aged 12 years and older

(CHMP, Positive Opinion)



CHMP issues positive opinion to Biocon's pertuzumab 420 mg concentrate solution for infusion to treat HER2-positive breast cancer across multiple disease stages

(FDA, Priority Review)



AstraZeneca's sBLA for IMFINZI in combination with EV gains Priority Review acceptance by FDA to treat MIBC



MEMBER OF PPF GROUP

(FDA, Orphan Drug, Fast Track)
SOTIO receives both FDA Orphan Drug designation and Fast Track designation for SOTI06, that treats STS and osteosarcoma



PRETZEL[®]
THERAPEUTICS

(FDA, Fast Track)
FDA gives Fast Track designation to Pretzel Therapeutics' PX578 to treat POLG disease

QUOIN

PHARMACEUTICALS

(FDA, Fast Track)
FDA grants Fast Track designation to Quoin Pharmaceuticals' QRX003 to treat peeling skin syndrome

Johnson & Johnson

(Phase 3, Results)
J&J's Ph3 study evaluating CAPLYTA to treat manic episodes with or without mixed features in adults with bipolar I disorder, demonstrates rapid symptom reduction vs. placebo at Week 3



(Phase 3, Results)



Novo Nordisk's Ph3 REIMAGINE 5 and REDEFINE 9 trials show once-weekly CAGRISEMA achieves superior weight loss compared to tirzepatide 5 mg, non-inferior HbA1c reduction, and up to 21.0% weight loss vs. 2.0% for placebo

(Phase 3, Results)



Ph3 FUSION trial of Ionis evaluating ulefnersen in ALS caused by mutations in FUS-ALS demonstrates improvements across primary and secondary endpoints, with changes in ALSFRS-R score from baseline compared to placebo

