



FDA approves OMVOH (mirikizumab-mrkz) for once-monthly, single-injection maintenance in adults with ulcerative colitis

(FDA, Approval)



Health Canada authorizes LEQEMBI (lecanemab) for treating early Alzheimer's disease in adults

(Health Canada, Approval)



CONEXXENCE and BOMYNTRA from Fresenius Kabi now FDA-designated interchangeable biosimilars to denosumab

(FDA, Interchangeable)



Celltrion's denosumab biosimilars, STOBOCLO and OSENVELT, receive FDA interchangeability designation

(FDA, Interchangeable)



(FDA, Fast Track)



JSKN003, a biparatopic HER2-targeting ADC from Alphamab, receives FDA Fast Track for platinum-resistant ovarian/peritoneal/fallopian-tube cancer (PROC)

REGENERON

(CRL)

Regeneron Pharmaceuticals receives FDA CRL for its pre-filled syringe version of EYLEA HD (aflibercept 8mg) for wet AMD/DME/DR



(Partnership)

4DMT grants Otsuka exclusive Asia-Pacific rights to 4D-150, its gene therapy candidate for large-market ophthalmology indications (wet AMD and diabetic macular edema)



(Partnership)

NeuroKaire enters R&D collaboration with Compass Pathways to develop personalized therapies for treatment-resistant depression

