

●▶ **Biocon Biologics**

*(PMDA, Approval)*

Biocon Biologics' Ustekinumab BS, Biosimilar to J&J's Stelara has been approved by Japan Health Authority (PMDA)

●▶ **Johnson & Johnson**

*(FDA , FTD)*

The US FDA has granted fast track designation to JNJ's posdinemab, a phosphorylated tau-directed monoclonal antibody (mAb) being investigated to treat patients with early Alzheimer's disease (AD)

●▶ **Marengo**

*(FDA , FTD)*

Marengo's STAR0602 received FDA fast track designation for the treatment of unresectable, locally advanced, or metastatic colorectal cancers TMB-H

●▶ **Dizal**

*(FDA , Priority Review)*

The US FDA has granted priority review to Dizal's NDA for sunvozertinib for the treatment of NSCLC

●▶ **Johnson & Johnson**

*(FDA , Priority Review)*

The US FDA has granted priority review to JNJ's nipocalimab for generalized myasthenia gravis treatment

●▶ **Sentynl Therapeutics**

*(FDA , Priority Review)*

The US FDA has granted priority review to Sentynl Therapeutics' NDA for CUTX-101 for the treatment of Menkes disease

●▶ **Rigel**

*(FDA, ODD)*

The US FDA has granted Orphan Drug Designation to Rigel's R289 for MDS





●▶ **MicuRx**

*(FDA, ODD)*

The US FDA has granted Orphan Drug Designation to MicuRx's MRX-5 for for the treatment of non-tuberculous mycobacteria (NTM) infections

●▶ **JW Therapeutics**

*(NMPA, Breakthrough Designation)*

JW Therapeutics' CARTEYVA received breakthrough therapy designation in China as second-line treatment for relapsed or refractory adult large B-cell lymphoma

●▶ **Synaffix+ Boehringer Ingelheim**

*(Partnership)*

Boehringer Ingelheim has licensed Synaffix's ADC technology to broden its oncology portfolio

●▶ **Menarini+ Insilico Medicine**

*(Partnership)*

Menarini+ Insilico Medicine expand partnership with second exclusive global license agreement for an AI asset in oncology innovation

●▶ **Synaffix + Mitsubishi Tanabe Pharma**

*(Agreement)*

Synaffix + Mitsubishi Tanabe Pharma enter into license agreement for ADC Technology

●▶ **Harbour BioMed + Windward Bio**

*(Agreement)*

Harbour BioMed + Windward Bio enter into a license agreement for HBM9378/SKB378, an anti-TSLP fully human antibody for immunological diseases

