VYUHPHARMA

# Highlights from the Week of 9th February - 16th February

MERCK

FDA approves Merck's KEYTRUDA and KEYTRUDA QLEX for certain patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, who have received one or two prior systemic treatment regimens

*( FDA, Approval )*

百奥泰 BIO-THERA

European Commission grants marketing authorization for Bio-Thera's GOTENFIA, a biosimilar referencing SIMPONI, for the treatment of various types of arthritis

*( EU, Approval )*

AMGEN

European Commission approves Amgen's UPLIZNA for the treatment of adult patients with generalized myasthenia gravis who are anti-AChR and anti-MuSK antibody positive

*( EU, Approval )*

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# Highlights from the Week of 9th February - 16th February

Takeda

FDA grants Priority Review for Takeda's oveporexton to treat narcolepsy type 1 patients who need new and different treatment options, with a PDUFA date in Q3 2026

*( FDA, Priority Review )*

HanchorBio

FDA grants Orphan Drug Designation to HanchorBio's HCB101 for the treatment of gastric cancer, including advanced gastric adenocarcinoma in both HER2-positive and HER2-negative subtypes

*( FDA, Orphan Drug )*

BIOCODEX
Driven by life, dedicated to life

Biocodex and THX Pharma announces a strategic licensing agreement to develop and commercialize treatments for three rare diseases, leveraging global footprint and specialized R&D pipelines

*( Collaboration )*

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# Highlights from the Week of 9th February - 16th February

sanofi

Sanofi acquires Dynavax for $15.50 per share, along with its adult vaccine candidates HEPLISAV-B, Z-1018 and additional vaccine pipeline projects

*( Acquisition )*

Alkermes

Alkermes acquires Avadel, a strategic move that accelerates Alkermes' entry into the sleep medicine market

*( Acquisition )*

Roche

Roche announces that the Phase 3 MAJESTY study for obinutuzumab in adults with primary membranous nephropathy successfully met its primary and secondary endpoints, achieving complete remission at 104 weeks

*( Phase 3, Result )*

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AstraZeneca

AstraZeneca announces positive results from the Phase 3 KALOS and LOGOS trials evaluating BREZTRI AEROSPHERE in patients with uncontrolled asthma, demonstrating significant improvements in lung function

*( Phase 3, Result )*