Highlights from the Week of May 19–23, 2025

VYUHPHARMA

(Global Licensing)

Pfizer entered into an exclusive global licensing agreement with China's 3SBio for the development, manufacturing and commercialization of SSGJ-707; 3SBio anticipates a Ph3 study in China in 2025

(FDA)

The FDA's ODAC voted in favor of J&J's DARZALEX FASPRO for high-risk smoldering multiple myeloma (HR-SMM); based on results from the Ph3 AQUILA study

(Partnership)

Northway Biotech partnered with Kaida BioPharma to manufacture KAD101 for hormone-driven cancers, such as ovarian cancer; the Ph1 trial is expected to start in Q4 2026 or Q1 2027

(Collaboration)

Mirai Bio partnered with Thermo Fisher for the development and manufacturing of its genetic medicines; Fisher to serve as a CDMO for cGMP services and commercial manufacturing

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(EMA, CHMP Opinion)

Roche recieved a positive CHMP opinion for Itovebi (inavolisib) as a first-line treatment in combination with palbociclib and fulvestrant for PIK3CA-mutated, ER-positive, HER2-negative advanced breast cancer

(FDA)

FDA granted an expanded interchangeable designation for Celltrion's Yuflyma (adalimumab-aaty), making it fully interchangeable with Humira across all marketed dosage forms and strengths, including PFS and AI

(Collaboration)

Viz.ai partnered with Sanofi and Regeneron to evaluate the AI-powered Viz COPD module for COPD; it will leverage EHR data and AI to enhance the detection and management of high-risk COPD patients

(FDA)

Fresenius Kabi's Otulfi (ustekinumab-aauz) received interchangeable designation from the FDA, allowing it to be substituted for the reference product, Stelara, without prescriber approval

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(Launch, Ustekinumab)

Biocon and Yoshindo launched Ustekinumab BS in Japan; Biocon had also entered into a settlement and licensing agreement with Janssen in 2024 to commercialize Ustekinumab in Japan

(NMPA, Approval)

China's NMPA approved Eylea 8 mg for the treatment of neovascular (wet) AMD, based on the Ph3 PULSAR trial; its is approved in the EU & UK, with additional regulatory applications underway in other markets

(Ph2, Alcohol Use Disorder)

Altimmune has initiated the RECLAIM Ph2 trial for pemvidutide in AUD; aims to enroll 100 subjects to evaluate the impact on heavy drinking days and WHO risk levels

(Acquisition)

AstraZeneca has finalized a $1B acquisition of EsoBiotec to revolutionize in vivo cell therapy

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