Vyuhpharma

Highlights from the week of
20th July - 27th July

GSK

(FDA, Approval)

GSK gets FDA approval for JIDEYTRO to treat adults with locally advanced or metastatic ROS1-positive NSCLC who received prior ROS1 kinase inhibitor

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Pfizer

(FDA, Priority Review)

FDA accepts Pfizer's sNDA, TALZENNA in combination with XTANDI for Priority Review, indicated to treat HRR gene-mutated mCRPC in US men

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Glenmark

(FDA, Approval)

FDA approves Glenmark's RYALTRIS Nasal Spray, 665 mcg/25 mcg per spray for expanded use, to treat symptoms of SAR in pediatrics aged 6 to less than 12 years

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AstraZeneca

(EU, Approval)

EC approves AstraZeneca's ETCAMAH in combination with a CDK 4/6 inhibitor for the treatment of adults with ER-positive, HER2-negative locally advanced or metastatic breast cancer

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Highlights from the week of
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Dyne Therapeutics

(FDA, Priority Review)

FDA accepts Dyne Therapeutics' BLA, DYNE-251 for Priority Review that treats DMD amenable to exon 51 skipping

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Roche

(CHMP, Positive Opinion)

CHMP provides positive recommendation for approval of Roche's SUSVIMO 100 mg/mL to treat nAMD

AstraZeneca

(CHMP, Positive Opinion)

CHMP recommends AstraZeneca and Daiichi Sankyo's ENHERTU in combination with pertuzumab for approval in the EU to treat adults with unresectable or metastatic HER2-positive breast cancer

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Samsung Bioepis

(Collaboration)

Samsung Bioepis collaborates with IntoCell to develop and commercialize SBE303, engineered to bind to Nectin-4, marking continued pipeline expansion

Vyuhpharma

Highlights from the week of
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Almirall *(Collaboration)*

Almirall and Certest Biotec collaborate to develop novel treatments for rare dermatologic diseases and recurrent cutaneous conditions through integrated mRNA and lipid nanoparticle platform

Halozyme *(Collaboration)*

Halozyme collaborates with Incyte globally, to evaluate additional subcutaneous formulations of INCA033989 in mutCALR-expressing MPNs with ENHANZE drug delivery technology

Johnson&Johnson *(Phase 3, Results)*

Johnson & Johnson's Phase 3 MonumenTAL-6 trial of TECVAYLI + TALVEY and TALVEY + pomalidomide in RRMM demonstrates clinically meaningful improvements in PFS and OS, reducing risk of disease progression or death by 89% for both arms vs. SOC

AstraZeneca *(Phase 3, Results)*

AstraZeneca's CLARITY-Gastric01 Phase 3 trial shows Sone-Ve clinically improves OS vs. choice of therapy in Claudin 18.2-positive advanced gastric cancer or EAC