Vyuhpharma

Highlights from the week of
19 January - 26 January

Ionis Pharmaceuticals *(EU, Approval)*

European Commission approves Ionis and Otsuka's DAWNZERA for the prevention of recurrent hereditary angioedema attacks in patients aged 12 years and older

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GSK *(EU, Approval)*

GSK's vaccine, AREXVY, receives European Commission approval for expanded use in adults aged 18 years and older to prevent lower respiratory tract disease caused by RSV

GSK *(NMPA, Approval)*

NMPA approves GSK's TRELEGY ELLIPTA as the first and only single inhaler triple therapy for the maintenance treatment of both asthma and chronic obstructive pulmonary disease in adults

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Akesobio *(NMPA, Approval)*

Akeso gains NMPA approval for its sNDA AK-111, a monoclonal antibody, to treat active ankylosing spondylitis

Vyuhpharma

Highlights from the week of
19 January - 26 January

Eli Lilly

(FDA, Breakthrough Therapy)

FDA grants Breakthrough Therapy designation to Eli Lilly's sofetabart mipitecan for the treatment of patients with platinum-resistant ovarian cancer

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Ouro Medicines

(FDA, Fast Track)

Ouro Medicines receives Fast Track designation for gamgertamig to treat autoimmune hemolytic anemia and immune thrombocytopenia

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BioNTech

(FDA, Fast Track)

BioNTech gains Fast Track designation for BNT-113, a mRNA cancer immunotherapy for HPV16 positive head and neck squamous cell carcinoma

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Celcuity

(FDA, Priority Review)

FDA grants Priority Review for Celcuity's gedatolisib to treat patients with HR+/HER2-/PIK3CA wild-type advanced breast cancer

Vyuhpharma

Highlights from the week of
19 January - 26 January

BioArctic

(FDA, Priority Review)

FDA grants Priority Review to BioArctic's sBLA for a subcutaneous starting dose of lecanemab-irmb to treat Alzheimer's disease

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Veloxis Pharmaceuticals

(FDA, Orphan Drug)

Veloxis Pharmaceuticals obtains Orphan Drug designation from FDA for VEL-101 to prevent organ rejection in patients receiving liver transplants

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Bayer

(FDA, Orphan Drug)

FDA grants Orphan Drug designation to Bayer and BlueRock Therapeutics' OpCT-001, an investigational (iPSC)-derived cell therapy for the treatment of primary photoreceptor diseases

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Immusoft

(FDA, Rare Pediatric Disease)

Immusoft receives Rare Pediatric Disease designation from the FDA for ISP-002, an engineered B cell therapy for the treatment of Hunter syndrome

Vyuhpharma

Highlights from the week of
19 January - 26 January

Novavax *(Licensing)*

Novavax enters into a $530 million license agreement with Pfizer for the use of its Matrix-M adjuvant technology in up to two disease areas

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GSK *(Acquisition)*

GSK enters into an agreement to acquire RAPT Therapeutics for $2.2 billion in order to gain ozureprubart, an anti-IgE antibody for food allergy prevention

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Sanofi *(Phase 3, Results)*

Sanofi's Phase 3 SHORE and COAST 2 trials for amlitelimab demonstrate significant efficacy and safety in patients with moderate-to-severe atopic dermatitis