VYUHPHARMA

Highlights from the Week of 20th April - 27th April

sanofi

FDA approves Sanofi's TZIELD sBLA to delay the onset of stage 3 type 1 diabetes in young children

(FDA, Approval)

AstraZeneca

AstraZeneca's SAPHNELO Pen for self-administration gets FDA approval for the treatment of adult patients with SLE on top of standard therapy

(FDA, Approval)

REGENERON

Regeneron receives accelerated approval from FDA for OTARMENI to treat patients with severe-to-profound and profound sensorineural hearing loss

(FDA, Accelerated Approval)

VYUHPHARMA

Highlights from the Week of 20th April - 27th April

moderna

EC grants marketing authorization to mCOMBRIAX for the prevention of influenza disease and COVID-19 caused by SARS-CoV-2 in individuals 50 years of age and older

(EU, Approval)

NOVARTIS

EC approves Novartis' RHAPSIDO for adult patients with chronic spontaneous urticaria who have an inadequate response to H1-antihistamines

(EU, Approval)

IPSEN
Innovation for patient care

Ipsen obtains conditional marketing authorization from the EC for OJEMDA to treat patients aged 6 months and older with pediatric low-grade-glioma or BRAF V600 mutation that progressed after one or more prior systemic therapies

(EU, Approval)

VYUHPHARMA

Highlights from the Week of 20th April - 27th April

Biocon

Biocon's BOSAYA 60 mg/mL injection in a prefilled syringe and VEVZUO 120 mg/1.7 mL injection for subcutaneous use in a single-dose vial receive Health Canada approval

(Health Canada, Approval)

CELLTRION

Celltrion obtains additional approval in Japan for STEQEYMA IV formulation, expanding its therapeutic scope and product competitiveness

(MHLW, Approval)

sanofi

CHMP recommends Sanofi's CENRIFKI for approval to treat secondary progressive multiple sclerosis without relapses

(CHMP, Positive Opinion)

VYUHPHARMA

Highlights from the Week of 20th April - 27th April

Pfizer

FDA accepts Pfizer and Astellas' sBLA for PADCEV in combination with KEYTRUDA or KEYTRUDA QLEX for Priority Review to treat muscle-invasive bladder cancer

(FDA, Priority Review)

pasithea THERAPEUTICS

FDA grants Rare Pediatric Disease designation to Pasithea Therapeutics' PAS-004 for the treatment of neurofibromatosis type-1

(FDA, Rare Pediatric Disease)

SERVIER

Servier acquires Day One Biopharmaceuticals for $2.5 billion, strengthening its leadership in low-grade glioma and expanding its oncology position

(Acquisition)

VYUHPHARMA

Highlights from the Week of 20th April - 27th April

SynSmart
Accelerating Discovery Solutions

SynSmart and Amporin Pharmaceuticals collaborate to develop breakthrough small molecule therapeutics to treat deadly degenerative diseases

(Collaboration)

AstraZeneca

AstraZeneca's Phase 3 MIRANDA trial demonstrates significant moderate-to-severe COPD exacerbations reduction with 300 mg tozorakimab on top of standard of care when compared to placebo

(Phase 3, Result)

REGENERON

Regeneron's Phase 3 NIMBLE trial evaluating subcutaneous cemdisiran in adults with gMG demonstrates efficacy with lasting benefit through week 24 when compared to placebo

(Phase 3, Result)

VYUHPHARMA

Highlights from the Week of 20th April - 27th April

novo nordisk®

Novo Nordisk's Phase 3 HIBISCUS trial evaluating oral etavopivat in adults and adolescents with SCD met both co-primary endpoints, demonstrating a 27% VOC annualized reduction and superior Hb response when compared to placebo

(Phase 3, Result)