Vyuhpharma

Highlights from the week of
12th Oct - 19th Oct



UCB

(FDA, Approval)

FDA approves UCB's ZILBRYSQ, an once-daily autoinjector, to treat gMG in adults who are anti-AChR antibody positive

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Genentech

(FDA, Approval)

Genentech's ENSPRYNG, the first and only at-home subcutaneous treatment option, gets FDA approval indicated to treat adults with TED

Viatris

(FDA, Approval)

FDA gives approval to Viatris' RYZUMVI to treat presbyopia in adults, expanding the product's indications

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Revolution Medicines

(CHMP, Positive Opinion)

Revolution Medicines receives positive CHMP opinion for its RASONQUE once-daily oral tablets to treat adults with metastatic pancreatic adenocarcinoma

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Sobi

(CHMP, Positive Opinion)

CHMP provides positive opinion for Sobi's indication extension of TRYNGOLZA as an adjunct to diet to treat sHTG

Ascendis Pharma

(CHMP, Positive Opinion)

Ascendis Pharma gets positive CHMP opinion for its once-weekly TransCon CNP to treat achondroplasia in children two years of age and older

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Regeneron

(CHMP, Positive Opinion)

Regeneron obtains positive CHMP opinion for alternative dosing schedule of LIBTAYO across all approved indications

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Leads Biolabs

(FDA, Fast Track)

VERIZON of Leads Biolabs secures FDA Fast Track designation for the treatment of advanced biliary tract cancer



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SAB BIO

(FDA, Fast Track)

FDA gives Fast track designation to SAB BIO's SAB-142 for the treatment of new-onset stage 3 T1D

Quoin Pharmaceuticals

(EU, Orphan Drug)

Quoin Pharmaceuticals' QRX003 gets Orphan Drug designation from EMA for the treatment of peeling skin syndrome

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Alaunos Therapeutics

(Acquisition)

Alaunos Therapeutics acquires Velaris Therapeutics, building a portfolio of ActRII-Fc ligand traps and complementary biologics for the treatment of pulmonary hypertension

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AstraZeneca

(Collaboration)

AstraZeneca collaborates with insitro for an upfront payment of $40M to identify novel drug targets and advance the design of new therapeutics for MASH and cardiomyopathies



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Vir Biotechnology

(Collaboration)

Vir Biotechnology partners with Gilead for an upfront payment of $135M, to discover and engineer three novel PRO-XTEN dual-masked TCE candidates for solid tumor-associated antigens

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Zealand Pharma

(Collaboration)

Zealand Pharma and Generate Biomedicines collaborate to design and develop multispecific protein therapeutics for obesity and other metabolic diseases



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