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Highlights from the week of
28th Sep - 05th Oct

Egetis Therapeutics

(FDA, Approval)

FDA approves Egetis Therapeutics' EMCITATE to treat peripheral thyrotoxicosis in patients with MCT8 deficiency

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Azurity Pharmaceuticals

(FDA, Approval)

Azurity Pharmaceuticals gets FDA approval for LAMLIQUE oral suspension that supports individualized epilepsy treatment

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Teva

(FDA, Approval)

Teva gets FDA approval for DEGEVMA to prevent bone complications in adults and skeletally mature adolescents with giant cell tumor of bone and to treat hypercalcemia of malignancy

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Bayer

(FDA, Priority Review)

FDA accepts Bayer's LYNKUET for Priority Review to treat moderate-to-severe VMS in women receiving endocrine therapy for HR+ breast cancer



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UTR Therapeutics *(FDA, Orphan Drug, Rare Pediatric Disease*

FDA grants Orphan Drug designation to UTR Therapeutics' UTRxMYCN M1-14 to treat soft tissue sarcoma, including RMS and Rare Pediatric Disease designation for RMS

Bayer *(FDA, EMA, Orphan Drug)*

Bayer's OpCT-001 receives Orphan Drug designations from the FDA and EMA to treat both syndromic and non-syndromic IRDs of the rod-dominant phenotype and the non-syndromic IRDs of the cone-dominant phenotype

mAbxience *(Acquisition)*

Fresenius acquires mAbxience, expanding manufacturing capabilities, technology transfer, enhancing quality and supply of biosimilars

STADA *(Collaboration)*

STADA collaborates with SBP for manufacturing and supplying biosimilars, expanding patient access across the EU, Switzerland, the UK, CIS, plus options for the US and selected other territories

Taiho Oncology *(Phase 3, Results)*

Ph3 AZTOUND trial from Taiho Oncology, evaluating ASTX030 in MDS or CMML, met its primary endpoint of AUC0-24 following oral azacitidine and cedazuridine compared with SC azacitidine



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Adare Pharma Solutions

(Collaboration)

Adare Pharma Solutions partners with OnDosis for CDMO services supporting the progression of OnDosis' extended-release product with mixed amphetamine salts

Chugai Pharmaceutical

(Collaboration)

Chugai Pharmaceutical and InxMed collaborate for SPYK04 to treat solid tumors, with Chugai receiving an upfront payment and royalties based on sales following product launch

Novo Nordisk

(Collaboration)

Novo Nordisk and Hengrui Pharma have entered into a for $2.6B partnership to develop, manufacture and commercialize HRS-1596 globally, excluding mainland China, Hong Kong, Macao and Taiwan

Merck

(Collaboration)

Merck and SciBrunch Therapeutics collaborate to develop, manufacture and commercialize SPR2015 worldwide, with an upfront payment of $400M



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AstraZeneca

(Collaboration)

AstraZeneca and Summit Therapeutics are partnering to accelerate ivonescimab development in combination with ADCs across tumour trpes and to evaluate Sone-Ve in combination with ivonescimab for GI cancers

Eli Lilly

(Phase 3, Results)

Eli Lilly's Ph3b ADtouch study evaluating EBGLYSS monotherapy met its primary and secondary endpoints, showing rapid improvements in adults and adolescents with moderate-to-severe hand and foot AD compared to placebo as measured by AHDCS scale

Eli Lilly

(Phase 3, Results)

Ph3 ACHIEVE-4 trial of Eli Lilly testing FOUNDAYO compared to titrated insulin glargine in type 2 diabetes and obesity or overweight at increased cardiovascular risk demonstrates non-inferior risk of MACE, improved A1C, weight and other key measures

Takeda

(Phase 3, Results)

Takeda's Ph3 LATITUDE studies investigating TAK-279 in adults with moderate-to-severe plaque psoriasis demonstrates superior efficacy compared to deucravacitinib with DLQI 0/1 vs. placebo and apremilast at week 4



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