

●► **Novo Nordisk**

*(FDA , Approval )*

The FDA has approved Novo Nordisk's OZEMPIC to reduce the risk of declining kidney function, kidney failure and cardiovascular death in adults with type 2 diabetes and chronic kidney disease

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●► **Roche**

*(FDA , Approval )*

The FDA has approved Roche's first companion diagnostic to identify metastatic breast cancer patients with HER2-ultralow expression who may benefit from ENHERTU treatment

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●► **Breckenridge Pharmaceutical**

*(FDA , Approval )*

Breckenridge Pharmaceutical announced FDA final approval for its Everolimus tablets for oral suspension, a generic version of Afinitor Disperz, for treating subependymal giant cell astrocytoma

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●► **Vertex**

*(FDA , Approval )*

Vertex Pharmaceuticals has received FDA approval for JOURNAVX (suzetrigine), a novel non-opioid treatment for moderate-to-severe acute pain in adults

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●► **Celltrion**

*(FDA , Approval )*

The FDA has approved Celltrion's AVTOZMA (CT-P47, tocilizumab-anoh), a biosimilar to ACTEMRA, in both IV and SC formulations, for treating rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and COVID-19





●▶ **Amgen**

*( EC , Approval )*

The EC has approved Amgen's Blincyto (blinatumomab) for the treatment of adults with newly diagnosed Philadelphia chromosome-negative, CD19-positive B-ALL

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●▶ **Beacon Therapeutics**

*( FDA , RMAT )*

The FDA has granted RMAT designation to Beacon Therapeutics' laru-zova (laruparetigene zovaparvovec) for the treatment of X-linked retinitis pigmentosa

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●▶ **Saol Therapeutics**

*( FDA , NDA Acceptance )*

Saol Therapeutics announced the FDA acceptance of NDA for SL1009 (sodium dichloroacetate oral solution) for the treatment of pyruvate dehydrogenase complex deficiency

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●▶ **IASO Bitherapeutics**

*( HSA , NDA Acceptance )*

IASO Bio has announced that Singapore's Health Sciences Authority (HSA) has accepted its NDA for Equecabtagene Autoleucel (FUCASO) for patients with relapsed and/or refractory multiple myeloma

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●▶ **Takeda and Neurocrine biosciences**

*( Partnership )*

Neurocrine Biosciences has announced an amendment to its agreement with Takeda concerning the development and commercialization of osavampator (NBI-1065845/TAK-653)

