

- ▶ **Pfizer** *(FDA, Approval)*
Pfizer's ADCETRIS combination regimen for the treatment of relapsed/refractory diffuse large B-cell lymphoma has received approval from the US FDA

- ▶ **Genetech** *(FDA, Approval)*
FDA has approved Genentech's Evrysdi tablet as the first and only tablet for treating SMA

- ▶ **Sanofi-Aventis** *(FDA, Approval)*
The FDA has approved Sanofi-Aventis' Merilog, the first rapid-acting insulin biosimilar, indicated for glycemic control in both adult and pediatric patients with diabetes mellitus

- ▶ **SpringWorks Therapeutics** *(FDA, Approval)*
SpringWorks' GOMEKLI received FDA approval for adults and children with NF1-PN

- ▶ **Glenmark + Cosmo** *(MHRA, Approval)*
Cosmos + Glenmark received MHRA approval to market Winlevi in the UK for the treatment of acne vulgaris in patients (>12 yrs age)



●▶ **CSL + Arcturus Therapeutics**

(EU, MAA)

CSL + Arcturus' KOSTAIVE, the first self-amplifying mRNA COVID-19 vaccine, received EU marketing approval

●▶ **Astellas**

(FDA, Label expansion)

FDA approved Astellas IZERVAY expanded use for the treatment of GA secondary to AMD

●▶ **Nektar Therapeutics**

(FDA, FTD)

Nektar's rezpegaldesleukin received FDA FTD for the treatment of adult and pediatric (12 yrs) patients with moderate-to-severe atopic dermatitis

●▶ **Lundbeck**

(FDA, FTD)

Lundbeck received FDA FTD for amlenetug for the treatment of MSA

●▶ **Pleopharma**

(FDA, FTD)

Pleopharma's PP-01, a potential first-in-class treatment, received FDA's FTD for the mitigation of cannabis withdrawal syndrome in patients with cannabis use disorder





●► **OnCusp Therapeutics**

(FDA, FTD)

OnCusp's CUSP06 received FDA's FTD for platinum-resistant ovarian cancer

●► **Tempest therapeutics**

(FDA, FTD)

Tempest's Amezalpat received FDA's FTD for the treatment of patients with HCC

●► **Glenmark**

(US, Launch)

Glenmark launched Evoclin's equivalent, clindamycin phosphate foam, 1% in the US

●► **AbbVie + Xilio**

(Collaboration)

AbbVie reached collaboration and option-to-license agreement with Xilio to develop novel tumor-activated mAb immunotherapies using T-cell engagers, leveraging Xilio's proprietary technology

●► **IDEAYA + Gilead**

(Collaboration)

IDEAYA entered clinical collaboration and supply agreement with Gilead for IDE397 in combination with Trodelvy in MTAP-deletion NSCLC



●► **DAAN + LigaChem**

(Licensing agreement)

DAAN signed an exclusive licensing agreement with LigaChem for ADC development of novel tumor-targeting mAb in solid tumor patients

●► **Boehringer Ingelheim**

(Clinical trials)

Topline Ph 3 FIBRONEER data on nerandomilast for the treatment of progressive pulmonary fibrosis met its endpoints; Boehringer Ingelheim to initiate NDA submission to FDA and other health authorities worldwide

●► **Pfizer + Astellas**

(Clinical trials result)

Pfizer + Astellas' PADCEV combined with KEYTRUDA demonstrates long-term efficacy in the first-line treatment of la/mUC

●► **Pfizer**

(Clinical trials result)

Pfizer reported Ph 3 results of TALZENNA combined with XTANDI, with clinically significant improvement in patients with mCRPC regardless of HRR gene mutations

