

●▶ **AbbVie** *(FDA, Approval)*

AbbVie's DECNUPAZ gains FDA approval to treat BPDCN, a hematologic malignancy with limited treatment options

●▶ **AstraZeneca** *(FDA, Approval)*

FDA gives approval to AstraZeneca's IMFINZI in combination with BCG induction and maintenance therapy for the treatment of adult patients with BCG-naïve, high-risk NMIBC

●▶ **Shionogi** *(FDA, Approval)*

Shionogi's XOCOVA receives FDA approval for post-exposure prophylaxis of COVID-19 in adults and adolescents 12 years and older

●▶ **MannKind** *(FDA, Approval)*

MannKind's AFREZZA inhalation powder is now FDA approved for use in children and adolescents aged 6 years and older with type 1 and 2 diabetes



●▶ **Zydus**

*(FDA, Priority Review)*

Zydus obtains Priority Review from the FDA for its saroglitazar NDA, indicated for the treatment of PBC in combination with UDCA as monotherapy or those unable to tolerate UDCA

●▶ **Sanofi**

*(FDA, Priority Review)*

FDA accepts Sanofi's venglustat for priority review as a treatment for type 3 Gaucher disease, a rare lysosomal storage disorder

●▶ **Autobahn**

*(FDA, Fast Track)*

Autobahn receives FDA Fast Track designation for elunetirom to treat depressive episodes associated with bipolar I or bipolar II disorder in adults

●▶ **Solu Therapeutics**

*(FDA, Fast Track)*

Solu Therapeutics' STX-0712 gets Fast Track designation from the FDA to treat relapsed or refractory CMML by directly depleting CCR2-positive malignant monocytes and bone marrow blasts



●▶ **Enterome**

*(FDA, Orphan Drug)*

FDA grants Orphan Drug designation to Enterome's EO2463 to treat indolent non-Hodgkin lymphoma in the low-tumor-burden, "watch-and-wait" setting

●▶ **RenovoRx**

*(FDA, Orphan Drug)*

FDA provides Orphan Drug designation to oxaliplatin from RenovoRx to treat pancreatic cancer

●▶ **CordenPharma**

*(Acquisition)*

CordenPharma acquires AmbioPharm, broadening its peptide API development and manufacturing capabilities for complex peptide programs in the US

●▶ **Pfizer**

*(Collaboration)*

Pfizer and Innovent Biologics enter into a strategic global licensing and collaboration agreement for the research, development and commercialization of 12 early-stage and de novo cancer medicines



●▶ **Olema Oncology**

*( Collaboration )*

Olema Oncology and Bayer announce a clinical trial collaboration and supply agreement to evaluate OP-3136 in combination with NUBEQA for mCRPC

●▶ **AstraZeneca**

*( Phase 3, Results )*

AstraZeneca's Phase 3 CARES trial showed that treatment with anselaminab as first-line therapy results in clinically meaningful benefits in adults with kappa light chain AL amyloidosis when added to standard of care PCD treatments compared to placebo

●▶ **UCB**

*( Phase 3, Results )*

Phase 3 PHOENYCS GO study by UCB and Biogen evaluating dapirolizumab pegol plus standard of care demonstrates significant improvements across endpoints in SLE activity at Week 48 when compared with placebo plus SOC

