



Cycle Pharma launches CAVHANZA in the US to offer dosing flexibility and tolerability for patients with Ph+ CML

(US, Launch)



Celltrion launches OMLYCLO 300 mg PFS and AI presentations in key European markets for CSU and allergic asthma

(EU, Launch)



J&J receives approval from the FDA for IMAAVY to treat wAIHA in patients aged 12 and older

(FDA, Approval)



Jazz Pharmaceuticals gets FDA approval for ZIIHERA regimens to treat adults with unresectable locally advanced or metastatic HER2+ gastroesophageal adenocarcinoma

(FDA, Approval)





Revolution Medicines gets FDA approval for RASONQUE to treat adults with metastatic pancreatic adenocarcinoma

(FDA, Approval)



FDA approves Gilead's BIXLENVO, a once-daily STR, for the treatment of HIV in virologically suppressed adults, including those on complex regimens

(FDA, Approval)



Priovent Therapeutics gains FDA approval for LISRAYA 30 mg to treat adults with dermatomyositis

(FDA, Approval)



Takeda receives FDA approval for MIMRYLO to treat erythrocytosis in adults with PV

(FDA, Approval)



FDA grants approval to Eli Lilly's MOUNJARO to lower the risk of MACE, including CV death, non-fatal heart attack, or non-fatal stroke, in adults with type 2 diabetes

(FDA, Approval)



EC gives approval to Zambon's HOPLEDO to treat adults with PD and those with moderate to severe motor fluctuations who have not been stabilized with oral DCC inhibitor-based treatment regimens

(EU, Approval)



FDA accepts GSK's JEMPERLI for priority review to treat previously untreated dMMR or MSI-H locally advanced rectal cancer

(FDA, Priority Review)



ADARx Pharmaceuticals obtains FDA Fast Track designation for onvuzosiran as a prophylaxis for hereditary angioedema attacks

(FDA, Fast Track)



(FDA, Fast Track)



FDA grants Fast Track designation to Sotio's SOTI06 for the treatment of soft tissue sarcoma

(FDA, Orphan Drug)



FDA grants Orphan Drug designation to Lakefront Biotherapeutics for gamgertamig to treat pemphigus

(EU, Orphan Drug)



EC provides Orphan Drug designation to Vanda Pharmaceuticals' insidolimab for the treatment of generalized pustular psoriasis

(EU, Orphan Drug)



Lundbeck secures Orphan designation from EC for asedebart to treat endogenous Cushing's syndrome

(MHLW, Orphan Drug)



Egetis Therapeutics receives Orphan Drug designation from Japan's MHLW for EMCITATE to treat MCT8 deficiency

(Acquisition)



argenx acquires Forte Biosciences, along with FBI02, expanding its immunology medicines portfolio

(Phase 3, Results)



AstraZeneca's Ph3 CROSSING trial evaluating TEZSPIRE in EoE shows improvements across co-primary and all key secondary endpoints vs. placebo at week 24 in both tested doses

