



FDA provides accelerated approval to Bayer's sevabertinib to treat locally advanced or metastatic NSCLC with HER2/ERBB2 tumors

(FDA, Accelerated Approval)



FDA accepts Takeda's TAK-279 under Priority Review to treat adults with moderate-to-severe plaque psoriasis

(FDA, Priority Review)



Genentech receives Priority Review from FDA for its sBLA, ENSPRYNG to treat MOGAD

(FDA, Priority Review)



Sobi obtains Fast Track designation from FDA for pacritinib to treat VEXAS syndrome

(FDA, Fast Track)



(FDA, Breakthrough Therapy)



FDA grants Breakthrough Therapy designation to UCB's CIMZIA to prevent placenta-mediated adverse pregnancy outcomes in pregnant women with APS who are positive for lupus anticoagulant

(Collaboration)



Aptar Pharma collaborates with Aceso Therapeutics to develop ACT-101 for cystic fibrosis

(Phase 3, Results)



AstraZeneca's Phase 3 OBERON and TITANIA trials show tozorakimab 300 mg reduce moderate-to-severe COPD exacerbations by 23% vs. placebo in patients with baseline BEC under 150

(Phase 3, Results)



Novo Nordisk's Phase 3 STEP Young trial shows once-weekly semaglutide with reduced-calorie diet and increased physical activity achieves superior BMI reduction at week 68 vs. placebo in children aged 6 to under 12 years with obesity



(Phase 3, Results)



AstraZeneca's Phase 3 ADAURA trial evaluating TAGRISSO shows OS benefit at eight years, reducing the risk of death compared to placebo by 47% in adjuvant treatment of early-stage EGFRm NSCLC

(Phase 3, Results)



Takeda's Phase 3 study evaluating oreporexton in NTI demonstrates improvements in wakefulness, sleepiness, cataplexy, disease severity and QOL measures over 12 weeks compared to placebo

(Phase 3, Results)



AstraZeneca's Phase 3 DESTINY-Lung04 trial evaluating ENHERTU demonstrates improved PFS and a 37.0% reduction in the risk of death compared with global SOC plus chemotherapy in patients with unresectable, locally advanced, or metastatic HER2-mutant NSCLC

