

CY 2024 CDER Breakthrough Therapy Calendar Year Approvals

Data as of March 31, 2024

Total of 7 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 213976	ORIGINAL-1	EOHILIA	BUDESONIDE	TAKEDA PHARMACEUTICALS USA INC	09-Feb-2024	For 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis
BLA 103976	SUPPLEMENT-5245	XOLAIR	OMALIZUMAB	GENENTECH INC	16-Feb-2024	Treatment of IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
NDA 208065	SUPPLEMENT-30	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	16-Feb-2024	In combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
NDA 217785	ORIGINAL-1	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	14-Mar-2024	In conjunction with diet and exercise, for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)
BLA 761244	SUPPLEMENT-3	SPEVIGO	SPESOLIMAB-SBZO	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	18-Mar-2024	Treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg
BLA 761363	ORIGINAL-1	WINREVAIR	SOTATERCEPT-CSRK	MERCK SHARP & DOHME LLC	26-Mar-2024	Treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events

NDA 218037	ORIGINAL-1	VOYDEYA	DANICOPAN	ALEXION PHARMACEUTICALS INC	29-Mar-2024	As add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH)
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