

CY 2025 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2025

Total of 37 Approvals

Appl Type Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 211243	SUPPL - 16	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	17-Jan-2025	The treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant
NDA 219209	ORIG - 1	JOURNAVX	SUZETRIGINE (VX-548)	VERTEX PHARMACEUTICALS INC	30-Jan-2025	The treatment of moderate to severe acute pain in adults
NDA 217906	ORIG - 1	EMBLAVEO	AZTREONAM AND AVIBACTAM	ABBVIE INC	07-Feb-2025	The treatment of complicated intraabdominal infections (cIAI) including those caused by the following susceptible gramnegative microorganisms: Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex, and Serratia marcescens. Approval of this indication is based on limited clinical safety and efficacy data for Emblaveo
NDA 219379	ORIG - 1	GOMEKLI	MIRDAMETINIB	SPRINGWORKS THERAPEUTICS INC	11-Feb-2025	Tablets 1mg for the treatment of adults and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection
NDA 219389	ORIG - 1	GOMEKLI	MIRDAMETINIB	SPRINGWORKS THERAPEUTICS INC	11-Feb-2025	Capsules 1 mg and 2 mg for the treatment of adults and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection
NDA 219304	ORIG - 1	ROMVIMZA	VIMSELTINIB	DECIPHERA PHARMACEUTICALS LLC	14-Feb-2025	The treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity
NDA 219488	ORIG - 1	CTEXLI	CHENODIOL	MIRUM PHARMACEUTICALS INC	21-Feb-2025	The treatment of cerebrotendinous xanthomatosis (CTX) in adults.

NDA 208692	SUPPL - 17	CABOMETYX	CABOZANTINIB	EXELIXIS INC	26-Mar-2025	To treat: <ul style="list-style-type: none"> • adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors. • adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors
NDA 216665	ORIG - 1	VYKAT XR	DIAZOXIDE CHOLINE	SOLENO THERAPEUTICS INC	26-Mar-2025	The treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome
NDA 219019	ORIG - 1	QFITLIA	FITUSIRAN	GENZYME CORP	28-Mar-25	for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors
BLA 761258	ORIG - 1		PENPULIMAB-KCQX	AKESO BIOPHARMA CO., LTD.	23-Apr-2025	or carboplatin and gemcitabine, for the firstline treatment of adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) As a single agent, for the treatment of adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based
BLA 761430	ORIG - 1	IMAAVY	NIPOCALIMAB-AAHU	JANSSEN BIOTECH, INC.	29-Apr-2025	For the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
BLA 761334	SUPPL - 4	ZYNYZ	RETIFANLIMAB-DLWR	INCYTE CORPORATION	15-May-2025	To add new indications for Zynyz (retifanlimab-dlwr): In combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC). As a single agent for the treatment of adult patients with locally recurrent or with metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy

NDA 212099	SUPPL - 8	NUBEQA	DAROLUTAMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	03-Jun-2025	Treatment of adult patients with metastatic castration-sensitive prostate cancer (mCSPC)
BLA 761432	ORIG - 1	ENFLONIA	CLESROVIMAB-CFOR	MERCK SHARP & DOHME LLC	09-Jun-2025	The prevention of respiratory syncytial virus (RSV) vlower respiratory tract disease in neonates and infants who are born during or entering their first RSV season
BLA 761367	ORIG - 1	ANDEMBRY	GARADACIMAB-GXII	CSL BEHRING LLC	16-Jun-2025	For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older
NDA 220018	ORIG - 1	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	18-Jun-2025	For pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition
NDA 220020	ORIG - 1	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	18-Jun-2025	For pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition
NDA-219155	ORIG - 1	ANZUPGO	DELGOCITINIB	LEO PHARMA AS	23-Jul-25	Treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable
BLA 761107	SUPPL - 18	GAMIFANT	EMAPALUMAB-LZSG	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	27-Jun-2025	For the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy