

CY 2024 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2024

Total of 31 Approvals

| Appl Type Number | Submission Type and Number | Proprietary Name | Established Name | Applicant | Approval Date | Use |
|------------------|----------------------------|------------------|-------------------------------|---|---------------|--|
| NDA 216165 | ORIG - 1 | EXBLIFEP | CEFEPIME AND ENMETAZOACTAM | ALLECRA THERAPEUTICS SAS | 22-Feb-2024 | Treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex |
| NDA 213217 | SUPPL - 11 | BRUKINSA | ZANUBRUTINIB | BEIGENE USA INC | 07-Mar-2024 | Treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy |
| NDA 217785 | ORIG - 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) |
| NDA 217865 | ORIG - 1 | DUVYZAT | GIVINOSTAT | ITALFARMACO SPA | 21-Mar-2024 | Treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older |
| NDA 218275 | ORIG - 1 | ZEVTERA | CEFTOBIPROLE MEDOCARIL SODIUM | BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL | 03-Apr-2024 | Treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: Staphylococcus aureus (methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, and Klebsiella pneumoniae |
| NDA 214511 | ORIG - 1 | LUMISIGHT | PEGULICIANINE | LUMICELL INC | 17-Apr-2024 | For fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery |

| | | | | | | |
|------------|-----------|-----------|--------------------------------------|--------------------------------------|-------------|--|
| BLA 761336 | ORIG - 1 | ANKTIVA | NOGAPENDEKIN ALFA INBAKICEPT-PMLN | ALTOR BIOSCIENCE LLC | 22-Apr-2024 | Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors |
| NDA 218623 | ORIG - 1 | LIBERVANT | DIAZEPAM | AQUESTIVE THERAPEUTICS | 26-Apr-2024 | Treatment of intermittent, stereotypical episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age |
| NDA 218709 | ORIG - 1 | XOLREMDI | MAVORIXAFOR | X4 PHARMACEUTICALS INC | 26-Apr-2024 | Treatment of patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes |
| NDA 217779 | ORIG - 1 | RYTELO | IMETELSTAT | GERON CORP | 06-Jun-2024 | Treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA) |
| NDA 218213 | SUPPL - 1 | AUGTYRO | REPOTRECTINIB | BRISTOL MYERS SQUIBB CO | 13-Jun-2024 | Treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy |
| NDA 211150 | SUPPL - 5 | WAKIX | PITOLISANT | HARMONY BIOSCIENCES LLC | 21-Jun-2024 | Treatment of excessive daytime sleepiness in patients 6 years of age and older with narcolepsy |
| BLA 761248 | ORIG - 1 | KISUNLA | DONANEMAB-AZBT | ELI LILLY AND COMPANY | 02-Jul-2024 | Treatment of Alzheimer's disease |
| NDA 217900 | ORIG - 1 | LEQSELVI | DEURUXOLITINIB | SUN PHARMACEUTICAL INDUSTRIES INC | 25-Jul-2024 | Treatment of adults with severe alopecia areata |
| NDA 218784 | ORIG - 1 | VORANIGO | VORASIDENIB | SERVIER PHARMACEUTICALS LLC | 06-Aug-2024 | Treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery including biopsy, sub-total resection, or gross total resection |

| | | | | | | |
|------------|----------|------------------------|-------------------------------------|------------------------------------|-------------|---|
| NDA 218590 | ORIG - 1 | ZURNAI | NALMEFENE | PURDUE PHARMA LP | 07-Aug-2024 | Emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression |
| NDA 214697 | ORIG - 1 | NEFFY | EPINEPHRINE | ARS PHARMACEUTICALS OPERATIONS INC | 09-Aug-2024 | Emergency treatment of type I allergic reactions, including anaphylaxis, in adults and pediatric patients who weigh 30 kg or greater |
| BLA 761411 | ORIG - 1 | NIKTIMVO | AXATILIMAB-CSFR | INCYTE CORPORATION | 14-Aug-2024 | Treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg |
| BLA 761306 | ORIG - 1 | EBGLYSS | LEBRIKIZUMAB-LBKZ | ELI LILLY AND COMPANY | 13-Sep-2024 | Treatment of moderate to severe atopic dermatitis |
| NDA 214927 | ORIG - 1 | MIPLYFFA | ARIMOCLOMOL | ZEVRA DENMARK A/S | 20-Sep-2024 | In combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients 2 years of age and older |
| NDA 219132 | ORIG - 1 | AQNEURSA | LEVACETYLLEUCINE | INTRABIO INC | 24-Sep-2024 | The treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg |
| NDA 217604 | ORIG - 1 | PYRIDOSTIGMINE BROMIDE | PYRIDOSTIGMINE BROMIDE | AMNEAL PHARMACEUTICALS LLC | 4-Oct-2024 | Pretreatment against the lethal effects of soman nerve agent poisoning in adults |
| BLA 761365 | ORIG - 1 | VYLOY | ZOLBETUXIMAB-CLZB | ASTELLAS PHARMA US INC | 18-Oct-2024 | In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test |
| NDA 213972 | ORIG - 1 | ORLYNVAH | SULOPENEM ETZADROXIL AND PROBENECID | ITERUM THERAPEUTICS US LTD | 25-Oct-2024 | Treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options |
| NDA 218944 | ORIG - 1 | REVUFORJ | REVUMENIB | SYNDAX PHARMACEUTICALS INC | 15-Nov-2024 | Treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older |

| | | | | | | |
|------------|------------|------------------------------|--------------------|---|-------------|--|
| BLA 761416 | ORIG - 1 | ZIIHERA | ZANIDATAMAB-HRII | JAZZ PHARMACEUTICALS IRELAND LIMITED | 20-Nov-2024 | Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC3+) biliary tract cancer as detected by an FDA approved test |
| BLA 761352 | ORIG - 1 | BIZENGRI | ZENOCUTUZUMAB-ZBCO | MERUS NV | 4-Dec-2024 | Treatment of adults with advanced, unresectable or metastatic non-small cell lung cancer harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy; and adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring an NRG1 gene fusion with disease progression on or after prior systemic therapy |
| NDA 218808 | ORIG - 1 | CRENESSITY- Oral Capsules | CRINECERFONT | NEUROCRINE BIOSCIENCES INC | 13-Dec-2024 | Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH) |
| NDA 218820 | ORIG - 1 | CRENESSITY- Oral Solution | CRINECERFONT | NEUROCRINE BIOSCIENCES INC | 13-Dec-2024 | Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH) |
| NDA 218614 | ORIG - 1 | TRYNGOLZA | OLEZARSEN | IONIS PHARMACEUTICALS INC | 19-Dec-2024 | Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS) |
| NDA 217806 | SUPPL - 13 | ZEPBOUND | TIRZEPATIDE | ELI LILLY AND CO | 20-Dec-2024 | Treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity |

NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded.