

CDER Fast Track Designation Approvals*

Data as of 12-31-2024

Total of 345 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 217806	SUPPL - 13	ZEPBOUND	TIRZEPATIDE	ELI LILLY AND CO	12/20/2024	Treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity
NDA 218614	ORIG - 1	TRYNGOLZA	OLEZARSEN	IONIS PHARMACEUTICALS INC	12/19/2024	Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)
NDA 218820	ORIG - 1	CRENESSITY- Oral Solution	CRINECERFONT	NEUROCRINE BIOSCIENCES INC	12/13/2024	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 218808	ORIG - 1	CRENESSITY- Oral Capsules	CRINECERFONT	NEUROCRINE BIOSCIENCES INC	12/13/2024	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)
BLA 761352	ORIG - 1	BIZENGRI	ZENOCUTUZUMAB-ZBCO	MERUS NV	12/4/2024	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
BLA 761416	ORIG - 1	ZIIHERA	ZANIDATAMAB-HRII	JAZZ PHARMACEUTICALS IRELAND LIMITED	11/20/2024	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC3+) biliary tract cancer as detected by an FDA approved test
NDA 218944	ORIG - 1	REVUFORJ	REVUMENIB	SYNDAX PHARMACEUTICALS INC	11/15/2024	Treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older
NDA 213972	ORIG - 1	ORLYNVAH	SULOPENEM ETZADROXIL AND PROBENECID	ITERUM THERAPEUTICS US LTD	10/25/2024	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
BLA 761365	ORIG - 1	VYLOY	ZOLBETUXIMAB-CLZB	ASTELLAS PHARMA US INC	10/18/2024	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 217604	ORIG - 1	PYRIDOSTIGMINE BROMIDE	PYRIDOSTIGMINE BROMIDE	AMNEAL PHARMACEUTICALS LLC	10/4/2024	Pretreatment against the lethal effects of soman nerve agent poisoning in adults
NDA 219132	ORIG - 1	AQNEURSA	LEVACETYLLUCINE	INTRABIO INC	9/24/2024	The treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg
NDA 214927	ORIG - 1	MIPLYFFA	ARIMOCLOMOL	ZEVRA DENMARK A/S	9/20/2024	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
BLA 761306	ORIG - 1	EBGLYSS	LEBRIKIZUMAB-LBKZ	ELI LILLY AND COMPANY	9/13/2024	Treatment of moderate to severe atopic dermatitis
BLA 761411	ORIG - 1	NIKTIMVO	AXATILIMAB-CSFR	INCYTE CORPORATION	8/14/2024	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
NDA 214697	ORIG - 1	NEFFY	EPINEPHRINE	ARS PHARMACEUTICALS OPERATIONS INC	8/9/2024	Emergency treatment of type I allergic reactions, including anaphylaxis, in adults and pediatric patients who weigh 30 kg or greater

NDA 218590	ORIG - 1	ZURNAI	NALMEFENE	PURDUE PHARMA LP	8/7/2024	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 218784	ORIG - 1	VORANIGO	VORASIDENIB	SERVIER PHARMACEUTICALS LLC SUN PHARMACEUTICAL INDUSTRIES INC	8/6/2024	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 217900	ORIG - 1	LEQSELVI	DEURUXOLITINIB	ELI LILLY AND COMPANY	7/25/2024	Treatment of adults with severe alopecia areata
BLA 761248	ORIG - 1	KISUNLA	DONANEMAB-AZBT	HARMONY BIOSCIENCES LLC	7/2/2024	Treatment of Alzheimer's disease
NDA 211150	SUPPL - 5	WAKIX	PITOLISANT		6/21/2024	Treatment of excessive daytime sleepiness in patients 6 years of age and older with narcolepsy
NDA 218213	SUPPL - 1	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	6/13/2024	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 217779	ORIG - 1	RYTELO	IMETELSTAT	GERON CORP	6/6/2024	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 218709	ORIG - 1	XOLREMDI	MAVORIXAFOR	X4 PHARMACEUTICALS INC	4/26/2024	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 218623	ORIG - 1	LIBERVANT	DIAZEPAM	AQUESTIVE THERAPEUTICS	4/26/2024	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
BLA 761336	ORIG - 1	ANKTIVA	NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ALTOR BIOSCIENCE LLC	4/22/2024	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 214511	ORIG - 1	LUMISIGHT	PEGULICIANINE	LUMICELL INC	4/17/2024	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
NDA 218275	ORIG - 1	ZEVTERA	CEFTOBIPROLE MEDOCARIL SODIUM	BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL	4/3/2024	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 217865	ORIG - 1	DUVYZAT	GIVINOSTAT	ITALFARMACO SPA	3/21/2024	Treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older
NDA 217785	ORIG - 1	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	3/14/2024	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 213217	SUPPL - 11	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	3/7/2024	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy
NDA 216165	ORIG - 1	EXBLIFEP	CEFEPIME AND ENMETAZOBACTAM	ALLECRA THERAPEUTICS SAS	2/22/2024	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 215064	ORIG - 1	FILSUVEZ	BIRCH TRITERPENES	AMRYT PHARMACEUTICALS INC	12/18/2023	Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older
NDA 217677	ORIG - 1	OGSIVEO	NIROGACESTAT	SPRINGWORKS THERAPEUTICS INC	11/27/2023	Treatment of adult patients with progressing desmoid tumors who require systemic treatment
NDA 203415	SUPPL - 22	XTANDI Capsules	ENZALUTAMIDE	ASTELLAS PHARMA US INC	11/16/2023	Treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis
NDA 213674	SUPPL - 10	XTANDI Tablets	ENZALUTAMIDE	ASTELLAS PHARMA US INC	11/16/2023	Treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis
NDA 218197	ORIG - 1	TRUQAP	CAPIVASERTIB	ASTRAZENECA PHARMACEUTICALS LP	11/16/2023	In combination with fulvestrant, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alteration as detected by an FDA-approved test following progression on at least
NDA 214520	ORIG - 1	DEFENCATH	TAUROLIDINE AND HEPARIN	CORMEDIX INC	11/15/2023	To reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC)
NDA 217564	ORIG - 1	FRUZAQLA	FRUQUINTINIB	TAKEDA PHARMACEUTICALS USA INC	11/8/2023	Treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy, an anti-VEGF therapy, and, if RAS wild type and medically appropriate, an anti-EGFR therapy
NDA 217806	ORIG - 1	ZEPBOUND	TIRZEPATIDE	ELI LILLY AND CO	11/8/2023	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related
NDA 215239	ORIG - 1	AGAMREE	VAMOROLONE	SANTHERA PHARMACEUTICALS	10/26/2023	Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older
NDA 204629	SUPPL - 40	JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	9/21/2023	To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression

BLA 761339	ORIG - 1	VEOPOZ	POZELIMAB-BBFG	REGENERON PHARMACEUTICALS INC	8/18/2023	Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
BLA 761345	ORIG - 1	ELREXFIO	ELRANATAMAB- BCMM	PFIZER INC	8/14/2023	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
NDA 217225	ORIG - 1	IZERVAY	AVACINCAPTAD PEGOL	IVERIC BIO INC	8/4/2023	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
NDA 217369	ORIG - 2	ZURZUVAE	ZURANOLONE	SAGE THERAPEUTICS INC	8/4/2023	Treatment of postpartum depression (PPD) in adults
NDA 217722	ORIG - 1	RIVIVE	NALOXONE HYDROCHLORIDE	HARM REDUCTION THERAPEUTICS INC	7/28/2023	Emergency treatment of opioid overdose
NDA 216993	ORIG - 1	VANFLYTA	QUIZARTINIB	DAIICHI SANKYO INC	7/20/2023	In combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an
BLA 761328	ORIG - 1	BEYFORTUS	NIRSEVIMAB-ALIP	ASTRAZENECA AB	7/17/2023	The prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
BLA 761309	ORIG - 1	COLUMVI	GLOFITAMAB-GXBM	GENENTECH INC	6/15/2023	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy
NDA 217188	ORIG - 1	PAXLOVID	NIRMATREL VIR AND RITONAVIR	PFIZER INC	5/25/2023	Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death
NDA 216974	ORIG - 1	XACDURO	SULBACTAM- DURLOBACTAM (SUL- DUR)	ENTASIS THERAPEUTICS INC	5/23/2023	Treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP), caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex

NDA 210136	ORIG - 1	BRIXADI	BUPRENORPHINE HYDROCHLORIDE	BRAEBURN INC	5/23/2023	Treatment of moderate to severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine
NDA 217470	ORIG - 1	OPVEE	NALMEFENE	INDIVIOR INC	5/22/2023	Emergency treatment treatment of known or suspected 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 depression
NDA 205422	SUPPL - 9	REXULTI	BREXPIRAZOLE	OTSUKA PHARMACEUTICAL CO LTD	5/10/2023	Treatment of agitation in patients diagnosed with dementia of Alzheimer's disease
BLA 761161	ORIG - 1	ELFABRIO	PEGUNIGALSIDASE ALFA	CHIESI FARMACEUTICI S.P.A.	5/9/2023	Treatment of adults with confirmed Fabry disease
NDA 202293	SUPPL - 26	FARXIGA	DAPAGLIFLOZIN	ASTRAZENECA AB	5/8/2023	To reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure
NDA 217660	ORIG - 1	TRIKAFTA	ELEXACAFTOR/TEZA CAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	4/26/2023	Treatment of cystic fibrosis (CF) in patients aged 2 years or older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data
NDA 215887	ORIG - 1	QALSODY	TOFERSEN	BIOGEN MA INC	4/25/2023	Treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene
BLA 761334	ORIG - 1	ZYNYZ	RETIFANLIMAB- DLWR	INCYTE CORP	3/22/2023	Treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma
NDA 217417	ORIG - 1	REZZAYO	REZAFUNGIN	CIDARA THERAPEUTICS INC	3/22/2023	Treatment of candidemia and invasive candidiasis in patients 18 years of age and older who have limited or no alternative options
NDA 217026	ORIG - 1	DAYBUE	TROFINETIDE	ACADIA PHARMACEUTICALS INC	3/10/2023	Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

NDA 208969	ORIG - 1		NALOXONE HYDROCHLORIDE	AMPHASTAR PHARMACEUTICALS INC	3/7/2023	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients
NDA 216718	ORIG - 1	SKYCLARYS	OMAVELOXOLONE	REATA PHARMACEUTICALS INC	2/28/2023	Treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older
NDA 217171	ORIG - 1	SYFOVRE	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	2/17/2023	Treatment of geographic atrophy secondary to age-related macular degeneration
BLA 761278	ORIG - 1	LAMZEDE	VELMANASE ALFA- TYCV	CHIESI FARMACEUTICI S.P.A.	2/16/2023	Treatment of the non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients
NDA 216059	ORIG - 1	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	1/27/2023	Treatment of adult patients with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor
NDA 217639	ORIG - 1	ORSERDU	ELACESTRANT	STEMLINE THERAPEUTICS INC	1/27/2023	Treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
BLA 761269	ORIG - 1	LEQEMBI	LECANEMAB-IRMB	EISAI INC	06-Jan-23	Treatment of Alzheimer's disease
NDA 215974	ORIG - 1	SUNLENCA	LENACAPAVIR TABLET AND INJECTABLE	GILEAD SCIENCES INC	12/22/2022	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
NDA 215973	ORIG - 1	SUNLENCA	LENACAPAVIR TABLET AND INJECTABLE	GILEAD SCIENCES INC	12/22/2022	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
NDA 214907	SUPPL - 2	CYTALUX	PAFOLACIANINE SODIUM	ON TARGET LABORATORIES INC	12/16/2022	As an adjunct for intraoperative identification of: Malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung

NDA 216340	ORIG - 1	KRAZATI	ADAGRASIB	MIRATI THERAPEUTICS INC	12/12/2022	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy
NDA 214900	SUPPL - 2	BREXAFEMME	IBREXAFUNGERP	SCYNEXIS INC	11/30/2022	For reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) in adult and post-menarchal pediatric females
NDA 215910	ORIG - 1	SEZABY	PHENOBARBITAL	SUN PHARMACEUTICAL INDUSTRIES LTD	11/17/2022	Treatment of neonatal seizures in term and preterm infants
BLA 761310	ORIG - 1	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	IMMUNOGEN, INC.	11/14/2022	Treatment of adult patients with folate- α (FR α)-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens
NDA 214801	ORIG - 1	LYTGOBI	FUTIBATINIB	TAIHO ONCOLOGY INC	9/30/2022	Treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
NDA 022231	ORIG - 1	TERLIVAZ	TERLIPRESSIN	MALLINCKRODT PHARMACEUTICALS IRELAND LTD	9/14/2022	To improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function
BLA 761261	ORIG - 1	XENPOZYME	OLIPUDASE ALFA-RPCP	GENZYME CORPORATION	8/31/2022	Treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients
NDA 215515	ORIG - 1	AMVUTTRA	VUTRISIRAN	ALNYLAM PHARMACEUTICALS INC	6/13/2022	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
NDA 214518	ORIG - 1	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	5/18/2022	Treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 3 kg
NDA 215446	ORIG - 1	RADICAVA ORS	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	5/12/2022	Treatment of amyotrophic lateral sclerosis
NDA 215152	ORIG - 1	VOQUEZNA TRIPLE PAK	VONOPRAZAN, AMOXICILLIN, AND CLARITHROMYCIN	PHATHOM PHARMACEUTICALS INC	5/3/2022	Treatment of Helicobacter pylori (H. pylori) infection in adults
NDA 215153	ORIG - 1	VOQUEZNA DUAL PAK	VONOPRAZAN AND AMOXICILLIN	PHATHOM PHARMACEUTICALS INC	5/3/2022	Treatment of Helicobacter pylori (H. pylori) infection in adults
NDA 215888	ORIG - 1	VIVJOA	OTESECONAZOLE	MYCOVIA PHARMACEUTICALS INC	4/26/2022	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential
NDA 215390	ORIG - 1	IGALMI	DEXMEDETOMIDINE	BIOXCEL THERAPEUTICS INC	4/5/2022	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults

NDA 213478	ORIG - 1	HYFTOR	SIROLIMUS	NOBELPHARMA CO LTD	3/22/2022	Treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older
BLA 761234	ORIG - 1	OPDUALAG	NIVOLUMAB AND RELATLIMAB-RMBW	BRISTOL-MYERS SQUIBB CO	3/18/2022	Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma
NDA 208712	ORIG - 1	VONJO	PACRITINIB	CTI BIOPHARMA CORP	2/28/2022	Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below $50 \times 10^9/L$
NDA 216196	ORIG - 1	PYRUKYND	MITAPIVAT	AGIOS PHARMACEUTICALS INC	2/17/2022	Treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency
NDA 215499	ORIG - 1	APRETUDE	CABOTEGRAVIR	VIIV HEALTHCARE CO	12/21/2021	HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and pediatric patients 12 to less than 18 years of age weighing at least 35 kg
BLA 761195	ORIG - 1	VYVGART	EFGARTIGIMOD ALFA	ARGENX BV	12/17/2021	Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive
NDA 215650	ORIG - 1	XACIATO	CLINDAMYCIN PHOSPHATE	DARE BIOSCIENCE INC	12/7/2021	Treatment of bacterial vaginosis in female patients 12 years of age and older
NDA 214907	ORIG - 1	CYTALUX	PAFOLACIANINE SODIUM	ON TARGET LABORATORIES INC	11/29/2021	As an optical imaging agent for use in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions
NDA 213312	ORIG - 1	FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES	AADI BIOSCIENCE INC	11/22/2021	Treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)
NDA 215358	ORIG - 2	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	10/29/2021	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation
NDA 215358	ORIG - 1	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	10/29/2021	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)
BLA 761197	ORIG - 1	SUSVIMO	RANIBIZUMAB	GENENTEC INC	10/22/2021	Treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD)
NDA 215310	ORIG - 1	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	9/15/2021	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy
NDA 213217	SUPPL - 5	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	9/14/2021	Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
NDA 213217	SUPPL - 4	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	8/31/2021	Treatment of adult patients with Waldenström's macroglobulinemia (WM)
NDA 213895	ORIG - 1	NA	VANCOMYCIN	XELLIA PHARMACEUTICALS APS	8/26/2021	Treatment of: <ul style="list-style-type: none"> • Clostridioides difficile-associated diarrhea • Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) • Septicemia • Infective Endocarditis • Skin and Skin Structure Infections • Bone Infections • Lower Respiratory Tract Infections

NDA 211192	SUPPL - 8	TIBSOVO	IVOSIDENIB	PHARMACEUTICALS LLC	8/25/2021	Treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation as detected by an FDA-approved test
NDA 202439	SUPPL - 35	XARELTO	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	8/23/2021	In combination with aspirin, to reduce the risk of major thromboticvascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with PAD, including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD
NDA 204629	SUPPL - 26	JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	8/18/2021	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction
NDA 212690	SUPPL - 6	XYWAV	CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES	JAZZ PHARMACEUTICALS INC	8/12/2021	Treatment of Idiopathic Hypersomnia (IH)
BLA 761194	ORIG - 1	NEXVIAZYME	AVALGLUCOSIDASE ALFA	GENZYME CORPORATION	8/6/2021	Treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)
BLA 761123	ORIG - 1	SAPHNELO	ANIFROLUMAB	ASTRAZENECA AB	7/30/2021	Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), receiving standard therapy
NDA 215498	ORIG - 1	BYLVAY	ODEVIXIBAT	ALBIREO AB	7/20/2021	Treatment of pruritus in patients 3 months of age and older, with progressive familial intrahepatic cholestasis (PFIC)
NDA 215341	ORIG - 1	KERENDIA	FINERENONE	BAYER HEALTHCARE PHARMACEUTICALS INC	7/9/2021	To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
BLA 761179	ORIG - 1	RYLAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)- RYWN	JAZZ PHARMACEUTICALS IRELAND LIMITED	6/30/2021	Treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase
BLA 761178	ORIG - 1	ADUHELM	ADUCANUMAB-	BIOGEN INC	6/7/2021	Treatment of Alzheimer's disease
NDA 214461	ORIG - 1	TEMBEXA TABLETS	BRINCIDOFOVIR	CHIMERIX INC	6/4/2021	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates
NDA 214460	ORIG - 1	TEMBEXA ORAL SUSPENSION	BRINCIDOFOVIR	CHIMERIX INC	6/4/2021	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates
NDA 214900	ORIG - 1	BREXAFEMME	IBREXAFUNGERP	SCYNEXIS INC	6/1/2021	Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis
NDA 214665	ORIG - 1	LUMAKRAS	SOTORASIB	AMGEN INC	5/28/2021	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy
NDA 214622	ORIG - 1	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC	5/28/2021	Treatment of adult patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangement as detected by an FDA approved test
NDA 215014	ORIG - 1	EMPAVELI	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	5/14/2021	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
NDA 211988	ORIG - 1	ZYNRELEF	BUPIVACAINE AND MELOXICAM	HERON THERAPEUTICS INC	5/12/2021	For soft tissue or periarticular instillation use to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty

NDA 212269	SUPPL - 1	FERRIPROX	DEFERIPRONE TABLETS	CHIESI USA INC	4/30/2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias
NDA 208030	SUPPL - 5	FERRIPROX	DEFERIPRONE ORAL SOLUTION	CHIESI USA INC	4/30/2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias
NDA 202293	SUPPL - 24	FARXIGA	DAPAGLIFLOZIN	ASTRAZENECA AB	4/30/2021	To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression
NDA 021825	SUPPL - 8	FERRIPROX	DEFERIPRONE	CHIESI USA INC	4/30/2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias
BLA 761115	SUPPL - 9	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS INC	4/13/2021	Treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed deathligand 1 (PD-L1) inhibitor
NDA 213026	ORIG - 1	AMONDYS 45	CASIMERSEN	SAREPTA THERAPEUTICS INC	2/25/2021	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping
NDA 213716	ORIG - 1	LUPKYNIS	VOCLOSPORIN	AURINIA PHARMACEUTICALS INC	1/22/2021	In combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis
NDA 212888	ORIG - 1	CABENUVA	CABOTEGRAVIR AND RILPIVIRINE - EXTENDED RELEASE INJECTABLE SUSPENSION	VIIV HEALTHCARE CO	1/21/2021	Treatment of HIV-1 infection in adults to replace their current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
NDA 212887	ORIG - 1	VOCABRIA	CABOTEGRAVIR TABLETS	VIIV HEALTHCARE CO	1/21/2021	In combination with Edurant (rilpivirine) 25 mg tablet for the short-term treatment of HIV1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine release injectable suspension)
NDA 214377	ORIG - 1	VERQUVO	VERICIGUAT	MERCK SHARP AND DOHME CORP	1/19/2021	To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%
BLA 761150	ORIG - 1	MARGENZA	MARGETUXIMAB - CMKB	MACROGENICS INC	12/16/2020	Treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease
NDA 214094	ORIG - 1	ORLADEYO	BEROTRALSTAT	BIOCRYST PHARMACEUTICALS INC	12/3/2020	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
NDA 214787	ORIG - 1	VEKLURY	REMDESIVIR	GILEAD SCIENCES INC	10/22/2020	For adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization
NDA 211150	ORIG - 2	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	10/13/2020	Treatment of cataplexy in adult patients with narcolepsy
BLA 125526	SUPPL - 17	NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE LLC	9/25/2020	Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for 6 months without an identifiable non-hematologic secondary cause

NDA 209445	SUPPL - 2	FETROJA	CEFIDEROCOL	SHIONOGI INC	9/25/2020	In patients 18 years of age and older for the treatment of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by the following susceptible Gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens
NDA 213227	ORIG - 1	DETECTNET	COPPER CU 64 DOTATATE	RADIOMEDIX INC	9/3/2020	For use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adults
BLA 761149	ORIG - 1	ENSPRYNG	SATRALIZUMAB-MWGE	GENENTECH INC	8/14/2020	Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
NDA 212154	ORIG - 1	VILTEPSO	VILTOLARSEN	NIPPON SHINYAKU CO LTD	8/12/2020	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
NDA 210730	ORIG - 1	OLINVYK	OLICERIDINE	TREVENA INC	8/7/2020	Management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate
NDA 213535	ORIG - 1	EVRYSDI	RISDIPLAM	GENENTECH INC	8/7/2020	Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older
BLA 761163	ORIG - 1	MONJUVI	TAFASITAMAB-CXIX	MORPHOSYS US INC	7/31/2020	In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT)
NDA 210365	SUPPL - 6	EPIDIOLEX	CANNABIDIOL	GW RESEARCH LTD	7/31/2020	Treatment of seizures associated with Dravet syndrome patients 1 year of age and older
NDA 209376	ORIG - 1	TRALEMENT	N/A	AMERICAN REGENT INC	7/2/2020	Trace elements injection indicated for adult and pediatric patients weighing at least 10 kilograms as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated
NDA 212950	ORIG - 1	RUKOBIA	FOSTEMSAVIR	VIIV HEALTHCARE CO	7/2/2020	Treatment of HIV-1 infection in heavily treatment experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
NDA 213687	ORIG - 1	DOJOLVI	TRIHEPTANOIN	ULTRAGENYX PHARMACEUTICAL INC	6/30/2020	As a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD)
NDA 212102	ORIG - 1	FINTEPLA	FENFLURAMINE	ZOGENIX INC	6/25/2020	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older
NDA 212306	SUPPL - 1	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	6/22/2020	Treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy
NDA 213400	ORIG - 1	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	6/18/2020	Treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies
NDA 212819	SUPPL - 2	RECARBRIO	IMIPENEM/CILASTATIN/RELEBACTAM	MERCK SHARP & DOHME CORP	6/4/2020	Treatment of Hospital-acquired Bacterial Pneumonia/Ventilator associated Bacterial Pneumonia (HABP/VABP) in adults due to the designated susceptible bacteria

NDA 204384	SUPPL - 13	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT LLC	5/27/2020	Treatment of pulmonary multi-drug resistant tuberculosis as part of combination therapy, in adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) to include patients ≥ 5 to <12 years of age and weighing at least 15 kg
BLA 125377	SUPPL - 110	YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB COMPANY	5/26/2020	In combination with nivolumab and 2 cycles of platinum-based chemotherapy, for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations
BLA 125554	SUPPL - 82	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	5/26/2020	In combination with ipilimumab and 2 cycles of platinum-based chemotherapy, for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations
NDA 213036	ORIG - 1	NA	ARTESUNATE FOR INJECTION	AMIVAS LLC	5/26/2020	Initial treatment of severe malaria in adult and pediatric patients
NDA 213973	ORIG - 1	QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS LLC	5/15/2020	Treatment of advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib
NDA 202293	SUPPL - 20	FARXIGA	DAPAGLIFLOZIN	ASTRAZENECA AB	5/5/2020	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction
BLA 761115	ORIG - 1	TRODELVY	SACITUZUMAB GOVITECAN	IMMUNOMEDICS INC	4/22/2020	Treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease
NDA 213411	ORIG - 1	TUKYSA	TUCATINIB	SEATTLE GENETICS INC	4/17/2020	In combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
NDA 211728	ORIG - 1	JELMYTO	MITOMYCIN	UROGEN PHARMA LTD	4/15/2020	Treatment of adult patients with low-grade upper tract urothelial cancer
BLA 761136	ORIG - 2	REBLOZYL	LUSPATERCEPT AAMT	CELGENE CORPORATION	4/3/2020	Treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
NDA 208341	SUPPL - 14	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES INC	3/19/2020	Treatment of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection in pediatric patients 6 years of age and older or weighing at least 17 kg
NDA 201699	SUPPL - 12	DIFICID	FIDAXOMICIN	CUBIST PHARMACEUTICALS LLC	1/24/2020	Treatment of clostridioides difficile-associated diarrhea (CDAD) in adults to include pediatric patients from 6 months to less than 18 years of age
BLA 761143	ORIG - 1	TEPEZZA	TEPROTUMUMAB-TRBW	THERAPEUTICS IRELAND DAC	1/21/2020	Treatment of thyroid eye disease
NDA 211635	ORIG - 1	VALTOCO	DIAZEPAM	NEURELIS INC	1/10/2020	Acute treatment of intermittent, stereotypic 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 6 years of age and older

NDA 212608	ORIG - 1	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	1/9/2020	Treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations
NDA 209500	ORIG - 1	CAPLYTA	LUMATEPERONE	INTRA-CELLULAR THERAPIES INC	12/20/2019	Treatment of Schizophrenia
BLA 761139	ORIG - 1	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO, INC.	12/20/2019	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
NDA 211970	ORIG - 1	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	12/12/2019	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
NDA 213137	ORIG - 1	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	11/25/2019	Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older
NDA 209445	ORIG - 1	FETROJA	CEFIDEROCOL	SHIONOGI INC	11/14/2019	Treatment of patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Enterobacter cloacae complex
NDA 213004	ORIG - 1	TALICIA	OMEPRazole MAGNESIUM, AMOXICILLIN, RIFABUTIN	REDHILL BIOPHARMA LTD	11/11/2019	Treatment of Helicobacter pylori infection in adults
BLA 761136	ORIG - 1	REBLOZYL	LUSPATERCEPT-AAMT	CELGENE CORPORATION	11/8/2019	Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.
NDA 208610	SUPPL-7	BAXDELA	DELAFLORACIN	MELINTA THERAPEUTICS INC	10/24/2019	Treatment of Community-Acquired Bacterial Pneumonia (CABP) in adults due to designated susceptible bacteria
NDA 212273	ORIG - 1	TRIKAFTA	ELEXACAFTOR/TEZA CAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	10/21/2019	Treatment of cystic fibrosis in patients 12 years and older who have at least one F508del mutation in the CFTR gene
NDA 022406	SUPPL - 33	XARELTO	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	10/11/2019	Prophylaxis of venous thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
NDA 210797	ORIG - 1	SCENESSE	AFAMELANOTIDE	CLINUVEL INC	10/8/2019	To increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP)
BLA 761068	SUPPL - 4	CRYSVITA	BUROSUMAB-TWZA	KYOWA KIRIN INC	9/27/2019	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older
NDA 205832	SUPPL-12	OFEV	NINTEDANIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	9/9/2019	To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease
NDA 211673	ORIG - 1	XENLETA IV	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	8/19/2019	Treatment of adults with Community-Acquired Bacterial Pneumonia (CABP) caused by designated susceptible microorganisms
NDA 211672	ORIG - 1	XENLETA Tablets	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	8/19/2019	Treatment of adults with Community-Acquired Bacterial Pneumonia (CABP) caused by designated susceptible microorganisms
NDA 212862	ORIG - 1		PRETOMANID	MYLAN IRELAND LTD	8/14/2019	As part of a combination regimen with bedaquiline and linezolid, for the treatment of adults with pulmonary extensively drug resistant (XDR), or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis
NDA 211150	ORIG - 1	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	8/14/2019	Treatment of excessive daytime sleepiness in adult with patients with narcolepsy

NDA 212099	ORIG - 1	NUBEQA	DAROLUTAMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	7/30/2019	Treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC)
NDA 212819	ORIG - 1	RECARBRIO	IMIPENEM/CILASTATIN/RELEBACTAM	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	7/16/2019	Treatment of patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by certain susceptible gram-negative bacteria:1) Complicated Urinary Tract Infections (cUTI), including pyelonephritis 2)Complicated Intra-abdominal Infections (cIAI)
NDA 212306	ORIG - 1	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	7/3/2019	In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody
BLA 761063	SUPPL - 3	EMGALITY	GALCANEZUMAB	ELI LILLY AND COMPANY	6/4/2019	Treatment of episodic cluster headache in adults
NDA 206829	SUPPL - 8	ZERBAXA	CEFTOLOZANE AND TAZOBACTAM	CUBIST PHARMACEUTICALS LLC	6/3/2019	Treatment of Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP)
NDA 211321	ORIG - 1	NAYZILAM	MIDAZOLAM HYDROCHLORIDE	UCB INC	5/20/2019	Acute treatment of intermittent, stereotypic 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 12 years of age and older
NDA 209321	ORIG - 1	RUZURGI	AMIFAMPRIDINE (3,4-DIAMINOPYRIDINE)	JACOBUS PHARMACEUTICAL CO INC	5/6/2019	Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age
NDA 211996	ORIG - 1	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	5/3/2019	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization
NDA 209379	ORIG - 1	SELENIUM ACID	SELENIUM ACID	AMERICAN REGENT INC	4/30/2019	Treatment of adult and pediatric patients as a source of selenium for parental nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated
NDA 210660	ORIG - 1	ELCYS	L-CYSTEINE HYDROCHLORIDE	EXELA PHARMA SCIENCES LLC	4/16/2019	To meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN); and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN
NDA 211243	ORIG - 1	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	3/5/2019	Treatment of treatment-resistant major depression
NDA 211962	ORIG - 1	VANCOMYCIN	VANCOMYCIN	XELLIA PHARMACEUTICALS APS	2/15/2019	Treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections, and lower respiratory tract infections
NDA 208711	ORIG - 1	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	2/13/2019	Treatment of fascioliasis in patients 6 years of age and older
BLA 761112	ORIG - 1	CABLIVI	CAPLACIZUMAB	ABLYNX NV	2/6/2019	Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy
NDA 211349	ORIG - 1	XOSPATA	GILTERITINIB	ASTELLAS PHARMA US INC	11/28/2018	Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test
NDA 210910	ORIG - 1	AEMCOLO	RIFAMYCIN	COSMO TECHNOLOGIES LTD	11/16/2018	Treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults
NDA 211172	ORIG - 1	TEGSEDI	INOTERSEN	AKCEA THERAPEUTICS INC	10/5/2018	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

BLA 761092	ORIG - 1	REVCovi	ELAPEGADEMASE-LVLR	LEADIANT BIOSCIENCES INC	10/5/2018	Treatment of Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID)
NDA 209817	ORIG - 1	NUZYRA	OMADACYCLINE	PARATEK PHARMACEUTICALS INC	10/2/2018	Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults due to the designated susceptible bacteria
NDA 209816	ORIG - 1	NUZYRA	OMADACYCLINE	PARATEK PHARMACEUTICALS INC	10/2/2018	Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults due to the designated susceptible bacteria
NDA 207356	ORIG - 1	ARIKAYCE	AMIKACIN LIPOSOME INHALATION SUSPENSION	INSMED INC	9/28/2018	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy for use in adults who have limited or no alternative treatment options
NDA 211155	ORIG - 2	COPIKTRA	DUVELISIB	VERASTEM INC	9/24/2018	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies
NDA 211155	ORIG - 1	COPIKTRA	DUVELISIB	VERASTEM INC	9/24/2018	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies
BLA 761104	ORIG - 1	LUMOXITI	MOXETUMOMAB PASUDOTOX- TDFK	ASTRAZENECA AB	9/13/2018	Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)
NDA 211109	ORIG - 1	XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS INC	8/27/2018	Treatment of complicated intra-abdominal infections in patients 18 years of age and older
BLA 761090	ORIG - 1	TAKHZYRO	LANADELUMAB-FLYO	DYAX CORP	8/23/2018	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older
BLA 761094	ORIG - 1	OXERVATE	CENEGERMIN-BKBJ	DOMPE FARMACEUTICI S.P.A.	8/22/2018	Treatment of neurotrophic keratitis
NDA 208623	ORIG - 1	GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS U.S INC	8/10/2018	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data
NDA 210922	ORIG - 1	ONPATTRO	PATISIRAN	ALNYLAM PHARMACEUTICALS INC	8/10/2018	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
NDA 210607	ORIG - 1	ARAKODA	TAFENOQUINE	60 DEGREES PHARMACEUTICALS LLC	8/8/2018	For the prophylaxis of malaria in patients 18 years and older
NDA 211358	ORIG - 1	ORKAMBI	LUMACFTOR/ IVACFTOR	VERTEX PHARMACEUTICALS INC	8/7/2018	Treatment of cystic fibrosis (CF) in patients 2 years and older, homozygous for the F508del-cystic fibrosis transmembrane conductance regulator (CFTR) mutation in the CFTR gene
NDA 210923	ORIG - 1	MULPLETA	LUSUTROMBOPAG	SHIONOGI INC	7/31/2018	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
NDA 209607	ORIG - 1	AZEDRA	IOBENGUANE I 131	PROGENICS PHARMACEUTICALS INC	7/30/2018	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy
NDA 210589	ORIG - 1	OMEGAVEN	FISH OIL TRIGLYCERIDES	FRESENIUS KABI USA LLC	7/27/2018	A source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC)
NDA 211192	ORIG - 1	TIBSOVO	IVOSIDENIB	AGIOS PHARMACEUTICALS INC	7/20/2018	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
NDA 208627	ORIG - 1	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	7/13/2018	Treatment of patients with human smallpox disease caused by variola virus

NDA 210365	ORIG - 1	EPIDIOLEX	CANNABIDIOL	GW RESEARCH LTD	6/25/2018	Treatment of seizures associated with Dravet syndrome in patients two years of age and older
BLA 761079	ORIG - 1	PALYNZIQ	PEGVALIASE-PQPZ	BIOMARIN PHARMACEUTICAL INC	5/24/2018	To reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management
NDA 209229	ORIG - 1	LUCEMYRA	LOFEXIDINE	US WORLDMEDS LLC	5/16/2018	Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
BLA 761068	ORIG - 1	CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX PHARMACEUTICAL INC	4/17/2018	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older
BLA 761065	ORIG - 1	TROGARZO	IBALIZUMAB-UIYK	THERATECHNOLOGIES INC	3/6/2018	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen
NDA 208855	ORIG - 1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	2/26/2018	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
NDA 210951	ORIG - 1	ERLEADA	APALUTAMIDE	JANSSEN BIOTECH INC	2/14/2018	Treatment of patients with high risk non-metastatic castration resistant prostate cancer
NDA 210491	ORIG - 1	SYMDEKO	TEZACAFTOR/ IVACAFTOR	VERTEX PHARMACEUTICALS INC	2/12/2018	Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence
NDA 208255	ORIG - 1	SYMFI LO	EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN PHARMACEUTICALS INC	2/5/2018	Treatment of HIV-1 infection in adult and pediatric patients weighing at least 35 kg
NDA 208700	ORIG - 1	LUTATHERA	¹⁷⁷ Lu- DOTA ⁰ -Tyr ³ - OCTREOTATE	ADVANCED ACCELERATOR APPLICATIONS USA INC	1/26/2018	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults
NDA 208910	ORIG - 1	FIRVANQ	VANCOMYCIN HYDROCHLORIDE	RXM THERAPEUTICS LLC	1/26/2018	Treatment of Clostridium difficile-associated diarrhea
NDA 209819	ORIG - 1	SUBLOCADE	BUPRENORPHINE	INDIVIOR INC	11/30/2017	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days
BLA 761047	ORIG - 1	MEPSEVII	VESTRONIDASE ALFA-VJBK	ULTRAGENYX PHARMACEUTICAL INC	11/15/2017	Treatment of Mucopolysaccharidosis type VII (MPS VII, Sly syndrome)
NDA 209939	ORIG - 1	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	11/8/2017	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMVseropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
NDA 208716	ORIG - 1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	9/28/2017	Treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
NDA 209363	ORIG - 1	SOLOSEC	SECNIDAZOLE	SYMBIOMIX THERAPEUTICS LLC	9/15/2017	Treatment of bacterial vaginosis in adult women.

NDA 209936	ORIG - 1	ALIQOPA	COPANLISIB HYDROCHLORIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	9/14/2017	Treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.
NDA 209776	ORIG - 1	VABOMERE	MEROPENEM AND VABORBACTAM	REMPEX PHARMACEUTICALS INC	8/29/2017	Treatment of patients 18 years of age and older with complicated Urinary Tract Infections (cUTI), including pyelonephritis
NDA 208558	ORIG - 1	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS LP	8/17/2017	Treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy; and treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
NDA 209401	ORIG - 1	VYXEOS	CYTARABINE AND DAUNORUBICIN	CELATOR PHARMACEUTICALS INC	8/3/2017	Treatment of patients with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)
NDA 209394	ORIG - 1	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	8/3/2017	Treatment of chronic hepatitis C virus (HCV) genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; and also for patients with HCV GT1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
NDA 209606	ORIG - 1	IDHIFA	ENASIDENIB	CELGENE CORP	8/1/2017	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
NDA 208383	ORIG - 1	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	6/23/2017	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE
NDA 208611	ORIG - 1	BAXDELA	DELAFLOXACIN INJECTION	MELINTA SUBSIDIARY CORP	6/19/2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208610	ORIG - 1	BAXDELA	DELAFLOXACIN TABLET	MELINTA THERAPEUTICS INC	6/19/2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208630	ORIG - 1	GLEOLAN	AMINOLEVULINIC ACID HYDROCHLORIDE	NX DEVELOPMENT CORP	6/6/2017	As an optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery
NDA 207997	ORIG - 1	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	4/28/2017	Treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
NDA 203085	SUPPL - 7	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	4/27/2017	Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
NDA 209241	ORIG - 1	INGREZZA	VALBENZAZINE	NEUROCRINE BIOSCIENCES INC	4/11/2017	Treatment of tardive dyskinesia
BLA 761053	ORIG - 1	OCREVUS	OCRELIZUMAB	GENENTECH INC	3/28/2017	Treatment of adult patients with primary progressive forms of multiple sclerosis
NDA 208447	ORIG - 1	ZEJULA	NIRAPARIB	TESARO INC	3/27/2017	Treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
BLA 761049	ORIG - 1	BAVENCIO	AVELUMAB	EMD SERONO INC	3/23/2017	Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
NDA 208794	ORIG - 1	XERMELO	TELOTTRISTAT ETHYL	LEXICON PHARMACEUTICALS INC	2/28/2017	Treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy

NDA 208685	ORIG - 1	EMFLAZA	DEFLAZACORT SUSPENSION	MARATHON PHARMACEUTICALS LLC	2/9/2017	Treatment of Duchenne muscular dystrophy in patients 5 years of age or older
NDA 208684	ORIG - 1	EMFLAZA	DEFLAZACORT TABLET	MARATHON PHARMACEUTICALS LLC	2/9/2017	Treatment of Duchenne muscular dystrophy in patients 5 years of age or older
NDA 208264	ORIG - 1	TEPADINA	THIOTEPA	ADIENNE SA	1/26/2017	To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia
NDA 208603	ORIG - 1	ARYMO ER	MORPHINE SULFATE	EGALET US INC	1/9/2017	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
NDA 209531	ORIG - 1	SPINRAZA	NUSINERSEN	BIOGEN	12/23/2016	Treatment of spinal muscular atrophy in pediatric and adult patients
BLA 761036	SUPPL - 4	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH	11/21/2016	In combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma
BLA 761046	ORIG - 1	ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME CORP	10/21/2016	To reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.
BLA 761038	ORIG - 1	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	10/19/2016	In combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery
NDA 206038	SUPPL - 5	ORKAMBI	IVACAFTOR AND LUMACAFTOR	VERTEX PHARMACEUTICALS	9/28/2016	Expands the indication to include 6-11 year old cystic fibrosis patients who are homozygous for the F508del mutation in the CFTR gene
NDA 206488	ORIG - 1	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS	9/19/2016	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
NDA 208341	ORIG - 1	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES	6/28/2016	Treatment of adult patients with chronic hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
NDA 207999	ORIG - 1	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS	5/27/2016	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA
NDA 208090	ORIG - 1	XTAMPZA ER	OXYCODONE	COLLEGIUM PHARMACEUTICAL	4/26/2016	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
NDA 208692	ORIG - 1	CABOMETYX	CABOZANTINIB	EXELIXIS	4/25/2016	Treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy
NDA 208114	ORIG - 1	DEFITELIO	DEFIBROTIDE SODIUM	JAZZ PHARMACEUTICALS	3/30/2016	Treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT)
BLA 125509	ORIG - 1	ANTHIM	OBILTOXAXIMAB	ELUSYS THERAPEUTICS	3/18/2016	Treatment of adult and pediatric patients with inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate
NDA 207865	ORIG - 1	EMEND	APREPITANT	MERCK SHARP AND DOHME CORP	12/17/2015	Prevention of chemotherapy induced nausea and vomiting in patients ages 6 months of age and older

NDA 208159	ORIG - 1	VISTOGARD	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	12/11/2015	Emergency treatment of adult and pediatric patients following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration
BLA 125561	ORIG - 1	KANUMA	SEBELIPASE ALFA	ALEXION PHARMACEUTICALS, INC.	12/8/2015	Treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency
BLA 125547	ORIG - 1	PORTRAZZA	NECITUMUMAB	ELI LILLY AND COMPANY	11/24/2015	In combination with gemcitabine and cisplatin for first-line treatment of patients with metastatic, squamous, non-small cell lung cancer
NDA 208411	ORIG - 1	NARCAN	NALOXONE HYDROCHLORIDE	ADAPT PHARMA OPERATIONS LTD	11/18/2015	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression
BLA 761036	ORIG - 1	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH INC	11/16/2015	Treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or are double refractory to a proteasome inhibitor and an immunomodulatory agent
NDA 208065	ORIG - 1	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	11/13/2015	Treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive-non-small-cell lung cancer (NSCLC), as detected by an FDA approved test, who have progressed on or after EGFR TKI therapy
BLA 125554**	SUPPL - 12	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	11/11/2015	Treatment of advanced renal cell carcinoma patients who have received prior antiangiogenic therapy
NDA 206192	ORIG - 1	COTELLIC	COBIMETINIB	GENENTECH INC	11/10/2015	Treatment, of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, in combination with vemurafenib. COTELLIC is not indicated for treatment of patients with wild-type BRAF melanoma
NDA 207561	ORIG - 1	GENVOYA	ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFVIR ALAFENAMIDE	GILEAD SCIENCES INC	11/5/2015	Treatment of HIV-1 infection in adults and pediatric patients 12 years of age or older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of GENVOYA
BLA 125513	ORIG - 1	STRENSIQ	ASFOTASE ALFA	ALEXION PHARMACEUTICALS INC	10/23/2015	Treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP)
NDA 207793	ORIG - 1	ONIVYDE	IRINOTECAN LIPOSOME	IPSEN BIOPHARMACEUTICALS INC	10/22/2015	In combination with 5-fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas that has progressed following gemcitabine-based therapy
BLA 125554**	SUPPL - 5	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB CO	10/9/2015	Treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with progression on or after platinum based chemotherapy
NDA 207981	ORIG - 1	LONSURF	TIPRACIL HYDROCHLORIDE AND TRIFLURIDINE	TAIHO ONCOLOGY INC	9/22/2015	Treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-oxaliplatin-and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
NDA 206843	ORIG - 1	DAKLINZA	DACLATASVIR	BRISTOL MYERS SQUIBB CO	7/24/2015	In combination with sofosbuvir for the treatment of chronic hepatitis C virus, genotype 3 infection

NDA 207620	ORIG - 1	ENTRESTO	SACUBITRIL AND VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	7/7/2015	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction
NDA 206038	ORIG - 1	ORKAMBI	IVACAFTOR AND LUMACAFTOR	VERTEX PHARMACEUTICALS INC	7/2/2015	Treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene.
NDA 206940	ORIG - 1	VIBERZI	ELUXADOLINE	ALLERGAN HOLDINGS UNLTD CO	5/27/2015	Treatment of irritable bowel syndrome with diarrhea (IBS-D)
NDA 206143	ORIG - 1	CORLANOR	IVABRADINE	AMGEN INC	4/15/2015	To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction $\leq 35\%$, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use
BLA 125527	ORIG - 1	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	3/4/2015	Treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.
NDA 207925	ORIG - 1	KAYLDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	3/3/2015	Treatment of cystic fibrosis patients 2 years and older who have one of the following mutations in CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R and R117H.
NDA 206494	ORIG - 1	AVYCAZ	AVIBACTAM AND CEFTAZIDIME	ALLERGAN SALES LLC	2/25/2015	Treatment complicated urinary tract infections (cUTIs), including pyelonephritis and complicated intra-abdominal infections (cIAs)
NDA 203952	ORIG - 1	DUOPA	CARBIDOPA AND LEVODOPA	ABBVIE INC	1/9/2015	Treatment of motor fluctuations in patients with advanced Parkinson's disease
BLA 125554	ORIG - 1	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	12/22/2014	Treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor
NDA 206829	ORIG - 1	ZERBAXA	CEFTOLOZANE AND TAZOBACTAM	CUBIST PHARMACEUTICALS LLC	12/19/2014	Treatment of complicated Urinary Tract Infections (cUTI) and complicated Intra-Abdominal Infections (cIAI)
NDA 206619	ORIG - 1	VIEKIRA PAK	DASABUVIR, OMBITASVIR, PARITAPREVIR, AND RITONAVIR	ABBVIE INC	12/19/2014	Treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis
NDA 206426	ORIG - 1	RAPIVAB	PERAMIVIR	BIOCRYST PHARMACEUTICALS INC	12/19/2014	Treatment of influenza infections
NDA 205832	ORIG - 1	OFEV	NINTEDANIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	10/15/2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 022535	ORIG - 1	ESBRIET	PIRFENIDONE	GENENTECH INC	10/15/2014	Treatment of idiopathic pulmonary fibrosis (IPF)
NDA 205834	ORIG - 1	HARVONI	LEDIPASVIR AND SOFOBUVIR	GILEAD SCIENCES INC	10/10/2014	Treatment of chronic hepatitis C, genotype 1 infection
NDA 203094	ORIG - 1	TYBOST	COBICISTAT	GILEAD SCIENCES INC	9/24/2014	Use as a CYP3A inhibitor indicated to increase systemic exposures of atazanavir in combination with other antiretroviral agents in the treatment of HIV-1 infection
NDA 206545	ORIG - 1	ZYDELIG	IDELALISIB	GILEAD SCIENCES INC	7/23/2014	Treatment of relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities
NDA 206256	ORIG - 1	BELEODAQ	BELINOSTAT	ACROTECH BIOPHARMA LLC	7/3/2014	Treatment of patients with relapsed or refractory peripheral t-cell lymphoma

NDA 202207**	SUPPL - 1	LYMPHOSEEK	TILMANOCEPT	NACIDEA BIOPHARMACEUTICALS INC	6/14/2014	For guiding sentinel lymph node biopsy, using a hand-held gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity
NDA 021883	ORIG - 1	DALVANCE	DALBAVANCIN HYDROCHLORIDE	ALLERGAN SALES LLC	5/23/2014	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
BLA 125476	ORIG - 1	ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS USA INC	5/20/2014	Inducing and maintaining clinical remission, inducing and maintaining clinical remission, improving the endoscopic appearance of the mucosa, and achieving corticosteroid-free remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids
NDA 204886	ORIG - 1	ZONTIVITY	VORAPAXAR SULFATE	ARALEZ PHARMACEUTICALS	5/8/2014	Reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD)
BLA 125477	ORIG - 1	CYRAMZA	RAMUCIRUMAB	ELI LILLY AND COMPANY	4/21/2014	Treatment of advanced gastric cancer or gastro-esophageal junction adenocarcinoma, as a single-agent after prior fluoropyrimidine-or platinum-containing therapy
NDA 205787	ORIG - 1	EVZIO	NALOXONE HYDROCHLORIDE	KALEO INC	4/3/2014	Treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, and for immediate administration as emergency therapy in settings where opioids may be present
NDA 204684	ORIG - 1	IMPAVIDO	MILTEFOSINE	KNIGHT THERAPEUTICS USA INC	3/19/2014	Treatment of visceral leishmaniasis due to Leishmania donovani, cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis and mucosal leishmaniasis due to Leishmania braziliensis
BLA 125390	ORIG - 1	MYALEPT	METRELEPTIN	AEGERION PHARMACEUTICALS INC	2/24/2014	Treatment of the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy
NDA 203202	ORIG - 1	NORTHERA	DROXIDOPA	LUNDBECK NA LTD	2/18/2014	Treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy
BLA 125460	ORIG - 1	VIMIZIM	ELOSULFASE ALFA	BIOMARIN PHARMACEUTICAL INC	2/14/2014	Treatment of patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)
NDA 205552	ORIG - 2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	2/12/2014	Treatment of patients with Chronic Lymphocytic Leukemia (CLL) who have received at least one prior therapy
NDA 204114	SUPPL - 1	MEKINIST	TRAMETINIB	GLAXO SMITH KLINE	1/8/2014	In combination with dabrafenib, for the treatment of patients with ions as detected by an FDA-approved test.
NDA 204671	ORIG - 1	SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INC	12/6/2013	Component of a combination antiviral regimen for the treatment of chronic hepatitis C infection
NDA 205123	ORIG - 1	OLYSIO	SIMEPREVIR	JANSSEN PRODUCTS LP	11/22/2013	Treatment of chronic hepatitis C (CHC) infection, as a component of a combination antiviral treatment regimen
NDA 205552	ORIG - 1	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	11/13/2013	Treatment of patients with Mantle Cell lymphoma (MCL)
NDA 204790	ORIG - 1	TIVICAY	DOLUTEGRAVIR	VIIV HEALTHCARE CO	8/12/2013	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40 kg

NDA 201292	ORIG - 1	GILOTRIF	AFATINIB	BOEHRINGER INGELHEIM	7/12/2013	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
NDA 022407	ORIG - 1	VIBATIV	TELAVANCIN	THERAVANCE BIOPHARMA ANTIBIOTICS INC	6/21/2013	Treatment of hospital acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of Staphylococcus aureus (including methicillin-susceptible and -resistant isolates) when alternative treatments are not suitable
NDA 204114	ORIG - 1	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	5/29/2013	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
NDA 202806	ORIG - 1	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	5/29/2013	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
NDA 203971	ORIG - 1	XOFIGO	RADIUM-223 DICHLORIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	5/15/2013	Treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease
NDA 203340	ORIG - 1	NYMALIZE	NIMODIPINE	ARBOR PHARMACEUTICALS LLC	5/10/2013	Treatment of subarachnoid hemorrhage
BLA 125319*	SUPPL - 62	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORP	5/9/2013	Treatment of Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older
NDA 204369	ORIG - 1	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	2/25/2013	Treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
BLA 125427	ORIG - 1	KADCYLA	TRASTUZUMAB EMTANSINE	GENENTECH INC	2/22/2013	Treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.
NDA 204026	ORIG - 1	POMALYST	POMALIDOMIDE	CELGENE CORP	2/8/2013	Treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy
NDA 203284	ORIG - 1	RAVICTI	GLYCEROL PHENYL BUTYRATE	HORIZON THERAPEUTICS LLC	2/1/2013	Nitrogen-binding adjunctive therapy for chronic management of adult and pediatric patients ≥2 years of age with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone
NDA 202292	ORIG - 1	MYTESI	CROFELEMER	NAPO PHARMACEUTICALS INC	12/31/2012	Treatment of symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy
NDA 204384	ORIG - 1	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT LLC	12/28/2012	Treatment of adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB) as part of a combination therapy regimen
NDA 202155	ORIG - 1	ELIQUIS	APIXABAN	BRISTOL MYERS SQUIBB CO	12/28/2012	To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
NDA 203469	ORIG - 1	ICLUSIG	PONATINIB	ARIAD PHARMACEUTICALS INC	12/14/2012	Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy

BLA 125349	ORIG - 1		RAXIBACUMAB	EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC	12/14/2012	Treatment of inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate
NDA 203756	ORIG - 1	COMETRIQ	CABOZANTINIB	EXELIXIS INC	11/29/2012	Treatment of patients with progressive, metastatic medullary thyroid cancer (MTC)
NDA 203585	ORIG - 1	SYNRIBO	OMACETAXINE MEPESUCCINATE	TEVA PHARMACEUTICALS INTERNATIONAL GMBH	10/26/2012	Treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI)
NDA 203085	ORIG - 1	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	9/27/2012	Treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy
NDA 203415	ORIG - 1	XTANDI	ENZALUTAMIDE	ASTELLAS PHARMA US INC	8/31/2012	Treatment of patients with metastatic castration-resistant prostate cancer who have previously previously received docetaxel
NDA 203100	ORIG - 1	STRIBILD	COBICISTAT, ELVITEGRAVIR, EMTRICITABINE, AND TENOFVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	8/27/2012	Treatment of HIV-1 infection in treatment-naïve adult patients
NDA 202714	ORIG - 1	KYPROLIS	CARFILZOMIB	ONYX THERAPEUTICS INC A WHOLLY OWNED SUB OF AMGEN INC	7/20/2012	Treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy
NDA 021752	SUPPL - 30	TRUVADA	EMTRICITABINE AND TENOFVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	7/16/2012	In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk
NDA 022175	ORIG - 1	PERTZYE	PANCRELIPASE	DIGESTIVE CARE INC	5/17/2012	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
NDA 022458	ORIG - 1	ELELYSO	TALIGLUCERASE ALFA	PFIZER INC	5/1/2012	Use as a long-term enzyme replacement therapy in patients with Type 1 Gaucher disease
NDA 021746	ORIG - 1	SURFAXIN	LUCINACTANT	WINDTREE THERAPEUTICS INC	3/6/2012	Prevention of respiratory distress syndrome in premature infants
NDA 022542	ORIG - 1	VIOKACE	PANCRELIPASE	FOREST LABORATORIES LLC	3/1/2012	Treatment of exocrine pancreatic insufficiency in adults due to chronic pancreatitis or pancreatectomy
NDA 022222	ORIG - 1	ULTRESA	PANCRELIPASE	FOREST LABORATORIES LLC	3/1/2012	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
NDA 203188	ORIG - 1	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	1/31/2012	Treatment of cystic fibrosis in patients age 6 years and older who have a G551D mutation in the CFTR gene
NDA 202324	ORIG - 1	INLYTA	AXITINIB	PF PRISM CV	1/27/2012	Treatment of advanced renal cell carcinoma after failure of one prior systemic therapy
BLA 125327	ORIG - 1	VORAXAZE	GLUCARPIDASE	BTG INTERNATIONAL INC	1/17/2012	Treatment of toxic (> 1 micromole per liter) plasma methotrexate concentrations in patients with delayed methotrexate clearance due to impaired renal function

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