CY 2023 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2023

This report reflects the data shown as it is identified in the database.

Selection Criteria:
User Response: Start Date: 1/1/2023 End Date: 12/31/2023
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 214373	BRENZAVVY	BEXAGLIFLOZIN	THERACOSBIO LLC	S	1/20/2023	ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 216059	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	P,O	1/27/2023	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MANTLE
NDA 217639	ORSERDU	ELACESTRANT	STEMLINE THERAPEUTICS INC	P	1/27/2023	FOR THE 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.
NDA 216951	JESDUVROQ	DAPRODUSTAT	GLAXOSMITHKLINE INTELLECTUAL PROPERTY NO 2 LTD ENGLAND	S	2/1/2023	FOR THE TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE IN ADULTS WHO HAVE BEEN RECEIVING DIALYSIS FOR AT LEAST FOUR MONTHS.
NDA 216403	FILSPARI	SPARSENTAN	TRAVERE THERAPEUTICS INC	P,O	2/17/2023	TO REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN TO CREATININE RATIO (UPCR) =1.5 G/G
NDA 216718	SKYCLARYS	OMAVELOXOLONE	REATA PHARMACEUTICALS INC	P,O	2/28/2023	FOR THE TREATMENT OF FRIEDREICH'S ATAXIA IN ADULTS AND ADOLESCENTS AGED 16 YEARS AND OLDER
NDA 216386	ZAVZPRET	ZAVEGEPANT	PFIZER INC	S	3/9/2023	ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS
NDA 217026	DAYBUE	TROFINETIDE	ACADIA PHARMACEUTICALS INC	P,O	3/10/2023	FOR THE TREATMENT OF RETT SYNDROME IN ADULTS AND PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER
NDA 217417	REZZAYO	REZAFUNGIN	CIDARA THERAPEUTICS INC	P,O	3/22/2023	FOR THE TREATMENT OF CANDIDEMIA AND INVASIVE CANDIDIASIS
NDA 217759	JOENJA	LENIOLISIB PHOSPHATE	PHARMING TECHNOLOGIES BV	P,O	3/24/2023	FOR THE TREATMENT OF ACTIVATED PHOSPHOINOSITIDE 3-KINASE DELTA (PI3KD) SYNDROME (APDS) IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER
NDA 215887	QALSODY	TOFERSEN	BIOGEN MA INC	P,O	4/25/2023	FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) IN ADULTS WHO HAVE A MUTATION IN THE SUPEROXIDE DISMUTASE 1 (SOD1) GENE.
NDA 216578	VEOZAH	FEZOLINETANT	ASTELLAS PHARMA US INC	P	5/12/2023	FOR THE TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS DUE TO MENOPAUSE
NDA 216675	MIEBO	PERFLUOROHEXYLOCTANE	BAUSCH AND LOMB INC	S	5/18/2023	FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF DRY EYE DISEASE (DED)
NDA 216974	XACDURO	SULBACTAM FOR INJECTION; DURLOBACTAM FOR INJECTION) CO-PACKAGED	ENTASIS THERAPEUTICS INC	P	5/23/2023	INDICATED 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 SUSCEPTIBLE ISOLATES OF ACINETOBACTER BAUMANNII-CALCOACETICUS COMPLEX.

NDA 216023	POSLUMA	FLOTUFOLASTAT F 18	BLUE EARTH DIAGNOSTICS LTD	S	5/25/2023	USE OF POSLUMA (FLOTUFOLASTAT F 18) FOR POSITRON EMISSION TOMOGRAPHY (PET) OF PROSTATE-SPECIFIC MEMBRANE ANTIGEN (PSMA) POSITIVE LESSIONS IN MEN WITH PROSTATE CANCER WITH SUSPECTED METASTATSIS WHO ARE CANDIDATES FOR INITIAL DEFINITIVE THERAPY OR WITH SUSPECTED RECURRENCE BASED ON ELEVATED SERUM PROSTATE-SPECIFIC ANTIGEN (PSA) LEVEL.
NDA 217188	PAXLOVID	NIRMATRELVIR AND RITONAVIR	PFIZER INC	P	5/25/2023	FOR THE 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 216203	INPEFA	SOTAGLIFLOZIN	LEXICON PHARMACEUTICALS INC	S	5/26/2023	INDICATED TO REDUCE THE RISK OF CARDIOVASCULAR DEATH, HOSPITALIZATION FOR HEART FAILURE, AND URGENT HEART FAILURE VISIT IN ADULTS WITH: * HEART FAILURE OR * TYPE 2 DIABETES MELLITUS, CHRONIC KIDNEY DISEASE, AND OTHER CARDIOVASCULAR RISK FACTORS
NDA 215830	LITFULO	RITLECITINIB	PFIZER INC	S	6/23/2023	FOR THE TREATMENT OF SEVERE ALOPECIA AREATA (AA) IN ADULTS AND ADOLESCENTS 12 YEARS AND OLDER.
NDA 216993	VANFLYTA	QUIZARTINIB	DAIICHI SANKYO INC	P,O	7/20/2023	IN COMBINATION WITH STANDARD CYTARABINE AND ANTHRACYCLINE INDUCTION AND CYTARABINE CONSOLIDATION, AND AS MAINTENANCE MONOTHERAPY FOLLOWING CONSOLIDATION CHEMOTHERAPY, THE TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) THAT IS FLT3 INTERNAL TANDEM DUPLICATION (ITD)-POSITIVE AS DETECTED BY AN FDA-APPROVED TEST.
NDA 217603	XDEMVY	LOTILANER	TARSUS PHARMACEUTICALS INC	S	7/24/2023	FOR THE TREATMENT OF DEMODEX BLEPHARITIS
NDA 217225	IZERVAY	AVACINCAPTAD PEGOL	IVERIC BIO INC	P	8/4/2023	FOR THE TREATMENT OF GEOGRAPHIC ATROPHY (GA) SECONDARY TO AGE-RELATED MACULAR DEGENERATION
NDA 217369	ZURZUVAE	ZURANOLONE	SAGE THERAPEUTICS INC	P	8/4/2023	FOR THE TREATMENT OF POSTPARTUM DEPRESSION (PPD) IN ADULTS
NDA 215559	SOHONOS	PALOVAROTENE	IPSEN BIOPHARMACEUTICALS INC	P,O	8/16/2023	FOR THE REDUCTION IN THE VOLUME OF NEW HETEROTOPIC OSSIFICATION IN ADULTS AND CHILDREN AGED 8 YEARS AND OLDER FOR FEMALES AND 10 YEARS AND OLDER FOR MALES WITH FIBRODYSPLASIA OSSIFICANS PROGRESSIVA (FOP).
NDA 217159	APHEXDA	MOTIXAFORTIDE	BIOLINERX LTD	S,O	9/8/2023	FOR USE IN COMBINATION WITH FILGRASTIM (G-CSF) TO MOBILIZE HEMATOPOIETIC STEM CELLS TO THE PERIPHERAL BLOOD FOR COLLECTION AND SUBSEQUENT AUTOLOGOUS TRANSPLANTATION IN PATIENTS WITH MULTIPLE MYELOMA.
NDA 216873	OJJAARA	MOMELOTINIB	GLAXOSMITHKLINE LLC	S,O	9/15/2023	FOR THE TREATMENT OF INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS (MF), INCLUDING PRIMARY MF OR SECONDARY MF (POST-POLYCYTHEMIA VERA AND POST-ESSENTIAL THROMBOCYTHEMIA), IN ADULTS WITH ANEMIA.
NDA 021164	EXXUA	GEPIRONE	FABRE KRAMER PHARMACEUTICALS INC	S	9/22/2023	FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER IN ADULTS
NDA 215842	RIVFLOZA	NEDOSIRAN	NOVO NORDISK INC	S,O	9/29/2023	TO LOWER URINARY OXALATE LEVELS IN CHILDREN 9 YEARS OF AGE AND OLDER AND ADULTS WITH PRIMARY HYPEROXALURIA TYPE 1 (PH1) AND RELATIVELY PRESERVED KIDNEY FUNCTION, E.G., EGFR = 30 ML/MIN/1.73 M2.
NDA 216956	VELSIPITY (ETRASIMOD)	ETRASIMOD	PFIZER INC	S	10/12/2023	FOR THE TREATMENT OF MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS IN ADULTS
NDA 216834	ZILBRYSQ (ZILUCOPLAN)	ZILUCOPLAN	UCB INC	S,O	10/17/2023	FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS IN ADULT PATIENTS WHO ARE ANTI-ACETYLCHOLINE RECEPTOR (ACHR) ANTIBODY POSITIVE

NDA 215239	AGAMREE (VAMOROLONE)	VAMOROLONE	CATALYST PHARMACEUTICALS INC	S,O	10/26/2023	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS 2 YEARS OF AGE AND OLDER
NDA 217564	FRUZAQLA (FRUQUINTINIB)	FRUQUINTINIB	TAKEDA PHARMACEUTICALS USA INC	P	11/8/2023	FOR THE 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 214520	TAUROLIDINE AND HEPARIN CATHETER LOCK SOLUTION	TAUROLIDINE AND HEPARIN) CATHETER LOCK SOLUTION	CORMEDIX INC	P	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). THIS DRUG IS INDICATED FOR USE IN A LIMITED AND SPECIFIC POPULATION OF PATIENTS.
NDA 218213	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	P,O	11/15/2023	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ROS1-POSITIVE NON-SMALL CELL LUNG CANCER
NDA 218197	TRUQAP	CAPIVASERTIB	ASTRAZENECA PHARMACEUTICALS LP	P	11/16/2023	TRUQAP (CAPIVASERTIB) TABLETS 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 ONE ENDOCRINE-BASED REGIMEN IN THE METASTATIC SETTING OR RECURRENCE ON OR WITHIN 12 MONTHS OF COMPLETING
NDA 217677	OGSIVEO	NIROGACESTAT	SPRINGWORKS THERAPEUTICS INC	P,O	11/27/2023	FOR ADULT PATIENTS WITH PROGRESSING DESMOID TUMORS WHO REQUIRE SYSTEMIC TREATMENT.
NDA 218276	FABHALTA	IPTACOPAN	NOVARTIS PHARMACEUTICALS CORP	P,O	12/5/2023	FOR THE TREATMENT OF ADULTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA
NDA 215064	FILSUVEZ	BIRCH TRITERPENES	CHIESI FARMACEUTICI SPA	P,O	12/18/2023	FOR THE TREATMENT OF WOUNDS ASSOCIATED WITH DYSTROPHIC AND JUNCTIONAL EPIDERMOLYSIS BULLOSA IN ADULT AND PEDIATRIC PATIENTS 6 MONTHS OF AGE AND OLDER.
NDA 217388	WAINUA	EPLONTERSEN	ASTRAZENECA AB	S,O	12/21/2023	FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (HATTR)

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761269	LEQEMBI (LECANEMAB-IRMB)	LECANEMAB-IRMB)	EISAI, INCORPORATED	P	1/6/2023	FOR THE TREATMENT OF ALZHEIMER'S DISEASE.
BLA 761278	LAMZEDE	VELMANASE ALFA-TYCV	CHIESI FARMACEUTICI S.P.A.	P,O	2/16/2023	FOR THE TREATMENT OF THE NON-CENTRAL NERVOUS SYSTEM MANIFESTATIONS OF ALPHA-MANNOSIDOSIS IN ADULT AND PEDIATRIC PATIENTS.
BLA 761334	ZYNYZ	RETIFANLIMAB-DLWR	INCYTE CORPORATION	P,O	3/22/2023	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC OR RECURRENT LOCALLY ADVANCED MERKEL CELL CARCINOMA.
BLA 761161	ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ	CHIESI FARMACEUTICI S.P.A.	P	5/9/2023	FOR THE TREATMENT OF ADULTS WITH CONFIRMED FABRY DISEASE
BLA 761324	EPKINLY	EPCORITAMAB-BYSP	GENMAB US, INC.	P	5/19/2023	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM INDOLENT LYMPHOMA, AND HIGH-GRADE B-CELL LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY

BLA 761309	COLUMVI	GLOFITAMAB-GXBM)	GENENTECH, INC.	P	6/15/2023	FOR THE 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.
BLA 761286	RYSTIGGO	ROZANOLIXIZUMAB-NOLI	UCB, INC.	P,O	6/26/2023	FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS (GMG) IN ADULT PATIENTS WHO ARE ANTI-ACETYLCHOLINE RECEPTOR (ACHR) OR ANTI-MUSCLE-SPECIFIC TYROSINE KINASE (MUSK) ANTIBODY POSITIVE.
BLA 761184	NGENLA (SOMATROGON-GHLA)	SOMATROGON-GHLA	PFIZER IRELAND PHARMACEUTICALS	S,O	6/27/2023	FOR THE TREATMENT OF PEDIATRIC PATIENTS AGED 3 YEARS AND OLDER WHO HAVE GROWTH FAILURE DUE TO AN INADEQUATE SECRETION OF ENDOGENOUS GROWTH HORMONE.
BLA 761328	BEYFORTUS	NIRSEVIMAB-ALIP	ASTRAZENECA AB	S	7/17/2023	PREVENTION OF 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 761342	TALVEY	TALQUETAMAB-TGVS	JANSSEN BIOTECH, INC.	P,O	8/9/2023	FOR THE 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.
BLA 761345	ELREXFIO	ELRANATAMAB-BCMM	PFIZER INC.	P,O	8/14/2023	FOR THE 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.
BLA 761339	VEOPOZ	POZELIMAB-BBFG	REGENERON PHARMACEUTICALS, INC.	P,O	8/18/2023	VEOPOZ IS A COMPLEMENT INHIBITOR INDICATED FOR THE 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 761204	POMBILITI	CIPAGLUCOSIDASE ALFA-ATGA	AMICUS THERAPEUTICS US, LLC	S	9/28/2023	IN COMBINATION WITH OPFOLDA, FOR THE TREATMENT OF ADULT PATIENTS WITH LATE-ONSET POMPE DISEASE (LYSOSOMAL ACID ALPHA-GLUCOSIDASE [GAA] DEFICIENCY) WEIGHING =40 KG AND WHO ARE NOT IMPROVING ON THEIR CURRENT ENZYME REPLACEMENT THERAPY (ERT).
BLA 761151	BIMZELX	BIMEKIZUMAB	UCB, INC.	S	10/17/2023	FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN ADULTS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY
BLA 761279	OMVOH	MIRIKIZUMAB-MRKZ	ELI LILLY AND COMPANY	S,O	10/26/2023	FOR ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC)
BLA 761240	LOQTORZI	TORIPALIMAB-TPZI	COHERUS BIOSCIENCES, INC.	P,O	10/27/2023	LOQTORZI, IN COMBINATION WITH CISPLATIN AND GEMCITABINE, FOR FIRST-LINE TREATMENT OF ADULTS WITH METASTATIC OR WITH RECURRENT, LOCALLY ADVANCED NASOPHARYNGEAL CARCINOMA (NPC); AND LOQTORZI, AS A SINGLE AGENT, FOR THE TREATMENT OF ADULTS WITH RECURRENT UNRESECTABLE OR METASTATIC NPC WITH DISEASE PROGRESSION ON OR AFTER A PLATINUM-CONTAINING CHEMOTHERAPY.

BLA 761134	RYZNEUTA	EFBEMALENOGRASTIM ALFA-VUXW)	EVIVE BIOTECHNOLOGY SINGAPORE PTE. LTD.	S	11/16/2023	TO DECREASE THE INCIDENCE OF INFECTION, AS MANIFESTED BY FEBRILE NEUTROPENIA, IN ADULT PATIENTS WITH NONMYELOID MALIGNANCIES RECEIVING MYELOSUPPRESSIVE ANTICANCER DRUGS ASSOCIATED WITH A CLINICALLY SIGNIFICANT INCIDENCE OF FEBRILE NEUTROPENIA

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).