CY 2022 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2022

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

Selection Criteria:
User Response: Start Date: 1/1/2022 End Date: 12/31/2022
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 214985	QUVIVIQ	DARIDOREXANT	IDORSIA PHARMACEUTICALS LTD	S	1/7/2022	FOR THE TREATMENT OF ADULT PATIENTS WITH INSOMNIA CHARACTERIZED BY DIFFICULTIES WITH SLEEP ONSET AND/OR SLEEP MAINTENANCE
NDA 213871	CIBINQO	ABROCITINIB	PFIZER INC	P	1/14/2022	FOR THE TREATMENT OF ADULTS WITH REFRACTORY, MODERATE-TO-SEVERE ATOPIC DERMATITIS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH OTHER SYSTEMIC DRUG PRODUCTS, INCLUDING BIOLOGICS, OR WHEN USE OF THOSE THERAPIES IS INADVISABLE
NDA 216196	PYRUKYND	MITAPIVAT	AGIOS PHARMACEUTICALS INC	P,O	2/17/2022	FOR THE TREATMENT OF HEMOLYTIC ANEMIA IN ADULTS WITH PYRUVATE KINASE (PK) DEFICIENCY
NDA 208712	VONJO	PACRITINIB	CTI BIOPHARMA CORP	P,O	2/28/2022	FOR THE 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 × 109/L.
NDA 215904	ZTALMY	GANAXOLONE	MARINUS PHARMACEUTICALS INC	P,O	3/18/2022	FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH CYCLIN-DEPENDENT KINASE-LIKE 5 (CDKL5) DEFICIENCY DISORDER (CDD) IN PATIENTS 2 YEARS OF AGE AND OLDER
NDA 215833	PLUVICTO	LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN)	ADVANCED ACCELERATOR APPLICATIONS USA INC A NOVARTIS CO	P	3/23/2022	FOR THE TREATMENT OF ADULT PATIENTS WITH PROSTATE-SPECIFIC MEMBRANE ANTIGEN (PSMA)-POSITIVE METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) WHO HAVE BEEN TREATED WITH ANDROGEN RECEPTOR (AR) PATHWAY INHIBITION AND TAXANE-BASED CHEMOTHERAPY
NDA 215888	VIVJOA	OTESECONAZOLE	MYCOVIA PHARMACEUTICALS INC	P	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 214998	CAMZYOS	MAVACAMTEN	MYOKARDIA INC	S,O	4/28/2022	FOR THE TREATMENT OF ADULTS WITH SYMPTOMATIC NEW YORK HEART ASSOCIATION (NYHA) CLASS II-III OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (HCM) TO IMPROVE FUNCTIONAL CAPACITY AND SYMPTOMS
NDA 215152	VOQUEZNA TRIPLE PAK	VONOPRAZAN, AMOXICILLIN, AND CLARITHROMYCIN)	PHATHOM PHARMACEUTICALS INC	P	5/3/2022	FOR THE TREATMENT OF HELICOBACTER PYLORI IN ADULTS
NDA 215866	MOUNJARO	TIRZEPATIDE	ELI LILLY AND CO	P	5/13/2022	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 215272	VTAMA	TAPINAROF	DERMAVANT SCIENCES INC	S	5/23/2022	FOR THE TOPICAL TREATMENT OF PLAQUE PSORIASIS IN ADULTS.
NDA 215515	AMVUTTRA	VUTRISIRAN	ALNYLAM PHARMACEUTICALS INC	S,O	6/13/2022	FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS.

NDA 214958	SOTYKTU	DEUCRAVACITINIB	BRISTOL MYERS SQUIBB CO	S	9/9/2022	FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY.
NDA 022231	TERLIVAZ	TERLIPRESSIN	MALLINCKRODT PHARMACEUTICALS IRELAND LTD	P,O	9/14/2022	TO IMPROVE KIDNEY FUNCTION IN ADULTS WITH HEPATORENAL SYNDROME WITH RAPID REDUCTION IN KIDNEY FUNCTION
NDA 216986	ELUCIREM	GADOPICLENOL	GUERBET	P	9/21/2022	AS A GADOLINIUM-BASED CONTRAST AGENT INDICATED IN ADULT AND PEDIATRIC PATIENTS AGED 2 YEARS AND OLDER FOR USE WITH MAGNETIC RESONANCE IMAGING (MRI) TO DETECT AND VISUALIZE LESIONS WITH ABNORMAL VASCULARITY IN: • THE CENTRAL NERVOUS SYSTEM (BRAIN, SPINE, AND ASSOCIATED TISSUES), • THE BODY (HEAD AND NECK, THORAX, ABDOMEN, PELVIS, AND MUSCULOSKELETAL SYSTEM).
NDA 215092	OMLONTI	OMIDENEPAG ISOPRPOPYL	SANTEN INC	S	9/22/2022	FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION
NDA 216660	RELYVRIO	SODIUM PHENYLBUTYRATE AND TAURURSODIOL	AMYLYX PHARMACEUTICALS INC	P,O	9/29/2022	FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) IN ADULT PATIENTS
NDA 214801	LYTGOBI	FUTIBATINIB	TAIHO ONCOLOGY INC	P,O	9/30/2022	FOR THE 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 215814	REZLIDHIA (OLUTASIDENIB)	OLUTASIDENIB	RIGEL PHARMACEUTICALS INC	S,O	12/1/2022	FOR THE 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 216340	KRAZATI (ADAGRASIB)	ADAGRASIB	MIRATI THERAPEUTICS INC	S,O	12/12/2022	FOR 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 215973	SUNLENCA (LENACAPAVIR)	LENACAPAVIR	GILEAD SCIENCES INC	P	12/22/2022	A HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) CAPSID INHIBITOR, IN COMBINATION WITH OTHER ANTIRETROVIRAL(S), IS INDICATED FOR THE 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 214375	XENOVIEW (HYPERPOLARIZED 129-XE)	HYPERPOLARIZED 129-XE	POLAREAN INC	S	12/23/2022	XENON XE 129 HYPERPOLARIZED WITH MAGNETIC RESONANCE IMAGING (MRI) FOR EVALUATION OF LUNG VENTILATION IN ADULTS AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION

BLA 761228	KIMMTRAK	TEBENTAFUSP-TEBN	IMMUNOCORE LIMITED	P,O	1/25/2022	FOR THE TREATMENT OF HLAA* 02:01-POSITIVE ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC UVEAL MELANOMA.
BLA 761235	VABYSMO	FARICIMAB-SVOA	GENENTECH, INC.	P	1/28/2022	FOR THE TREATMENT OF NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION AND TREATMENT OF DIABETIC MACULAR EDEMA
BLA 761164	ENJAYMO	SUTIMLIMAB-JOME	BIOVERATIV THERAPEUTICS, INC.	P,O	2/4/2022	INDICATED TO DECREASE THE NEED FOR RED BLOOD CELL (RBC) TRANSFUSION DUE TO HEMOLYSIS IN ADULTS WITH COLD AGGLUTININ DISEASE (CAD).
BLA 761234	OPDUALAG	NIVOLUMAB AND RELATLIMAB-RMBW	BRISTOL-MYERS SQUIBB COMPANY	P,O	3/18/2022	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE OR OLDER WITH UNRESECTABLE OR METASTATIC MELANOMA
BLA 761261	XENPOZYME	OLIPUDASE ALFA-RPCP	GENZYME CORPORATION	P,O	8/31/2022	FOR TREATMENT OF NON–CENTRAL NERVOUS SYSTEM MANIFESTATIONS OF ACID SPHINGOMYELINASE DEFICIENCY (ASMD) IN ADULT AND PEDIATRIC PATIENTS.
BLA 761244	SPEVIGO	SPESOLIMAB-SBZO	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	P,O	9/1/2022	FOR THE TREATMENT OF GENERALIZED PUSTULAR PSORIASIS (GPP) FLARES IN ADULTS
BLA 761127	DAXXIFY	DAXIBOTULINUMTOXINA-LANM	REVANCE THERAPEUTICS, INC.	S	9/7/2022	FOR THE TREATMENT OF MODERATE TO SEVERE GLABELLAR LINES ASSOCIATED WITH CORRUGATOR AND/OR PROCERUS MUSCLE ACTIVITY IN ADULT PATIENTS
BLA 761148	ROLVEDON	EFLAPEGRASTIM-XNST	SPECTRUM PHARMACEUTICALS, INC.	S	9/9/2022	TO DECREASE THE INCIDENCE OF INFECTION, AS MANIFESTED BY FEBRILE NEUTROPENIA, IN PATIENTS WITH NON-MYELOID MALIGNANCIES RECEIVING MYELOSUPPRESSIVE ANTI-CANCER DRUGS
BLA 761289	IMJUDO	TREMELIMUMAB-ACTL	ASTRAZENECA AB	P,O	10/21/2022	IN COMBINATION WITH DURVALUMAB, FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA (UHCC)
BLA 761291	TECVAYLI	TECLISTAMAB-CQYV	JANSSEN BIOTECH, INC.	P,O	10/25/2022	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 761310	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	IMMUNOGEN, INC.	P,O	11/14/2022	FOR THE TREATMENT OF ADULT PATIENTS WITH FRA POSITIVE, PLATINUM RESISTANT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WHO HAVE RECEIVED ONE TO THREE PRIOR SYSTEMIC TREATMENT REGIMENS
BLA 761183	TZIELD	TEPLIZUMAB-MZWV	PROVENTION BIO, INC.	P	11/17/2022	TO DELAY THE ONSET OF STAGE 3 TYPE 1 DIABETES (T1D) IN ADULTS AND PEDIATRIC PATIENTS AGED 8 YEARS AND OLDER WITH STAGE 2 T1D.
BLA 761263	LUNSUMIO	MOSUNETUZUMAB-AXGB	GENENTECH, INC.	P,O	12/22/2022	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY
BLA 761192	NEXOBRID	DEBRASE	MEDIWOUND, LTD.	S,O	12/28/2022	FOR ESCHAR REMOVAL IN ADULTS WITH DEEP PARTIAL THICKNESS (DPT) AND/OR FULL THICKNESS (FT) THERMAL BURNS
BLA 761238	BRIUMVI	UBLITUXIMAB-XIIY	TG THERAPEUTICS, INC.	S	12/28/2022	FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, IN ADULTS

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).