CY 2021 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2021

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

Selection Criteria:
User Response: Start Date: 1/1/2021 End Date: 12/31/2021
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 214377	VERQUVO	VERICIGUAT	MERCK SHARP AND DOHME CORP	P	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%
NDA 212888	CABENUVA	CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION	VIIV HEALTHCARE CO	P	1/21/2021	IS INDICATED AS A COMPLETE REGIMEN FOR THE 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 213716	LUPKYNIS	VOCLOSPORIN	AURINIA PHARMACEUTICALS INC	P	1/22/2021	INDICATED IN COMBINATION WITH A BACKGROUND IMMUNOSUPPRESSIVE THERAPY REGIMEN FOR THE TREATMENT OF ADULT PATIENTS WITH ACTIVE LUPUS NEPHRITIS
NDA 214096	TEPMETKO	TEPOTINIB	EMD SERONO INC	P,O	2/3/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) HARBORING
NDA 213176	UKONIQ	UMBRALISIB	TG THERAPEUTICS INC	P,O	2/5/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL) WHO HAVE RECEIVED AT LEAST ONE PRIOR ANTI-CD20- BASED REGIMEN ORIGINAL 2 – TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) WHO HAVE RECEIVED AT LEAST THREE PRIOR LINES OF SYSTEMIC THERAPY
NDA 214200	COSELA	TRILACICLIB	G1 THERAPEUTICS INC	P	2/12/2021	TO DECREASE THE INCIDENCE OF CHEMOTHERAPY-INDUCED MYELOSUPPRESSION IN ADULT PATIENTS WHEN ADMINISTERED PRIOR TO A PLATINUM/ETOPOSIDE-CONTAINING REGIMEN OR TOPOTECAN-CONTAINING REGIMEN FOR EXTENSIVE-STAGE SMALL CELL LUNG CANCER
NDA 213026	AMONDYS 45	CASIMERSON	SAREPTA THERAPEUTICS INC	P,O	2/25/2021	FOR THE 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 214018	NULIBRY	FOSDENOPTERIN	ORIGIN BIOSCIENCES INC	P,O	2/26/2021	TO REDUCE THE RISK OF MORTALITY IN PATIENTS WITH MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A
NDA 214383	PEPAXTO	MELPHALAN FLUFENAMIDE	ONCOPEPTIDES AB	P,O	2/26/2021	IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR LINES OF THERAPY AND WHOSE DISEASE IS REFRACTORY TO AT LEAST ONE PROTEASOME INHIBITOR, ONE IMMUNOMODULATORY AGENT, AND ONE CD-38 DIRECTED MONOCLONAL ANTIBODY
NDA 212994	AZSTARYS	SERDEXMETHYLPHENIDATE AND DEXMETHYLPHENIDATE	COMMAVE THERAPEUTICS SA	S	3/2/2021	FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER
NDA 212904	FOTIVDA	TIVOZANIB	AVEO PHARMACEUTICALS INC	S	3/10/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY ADVANCED RENAL CELL CARCINOMA (RCC) FOLLOWING TWO OR MORE PRIOR SYSTEMIC THERAPIES

NDA 213498	PONVORY	PONESIMOD	JANSSEN PHARMACEUTICALS INC	S	3/18/2021	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
NDA 214231	ZEGALOGUE	DASIGLUCAGON	ZEALAND PHARMA AS	S	3/22/2021	FOR THE TREATMENT OF SEVERE HYPOGLYCEMIA IN PEDIATRIC AND ADULT PATIENTS WITH DIABETES AGED 6 YEARS AND ABOVE
NDA 211964	QELBREE	VILOXAZINE	SUPERNUS PHARMACEUTICALS INC	S	4/2/2021	FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN PEDIATRIC PATIENTS 6 TO 17 YEARS OF AGE
NDA 214154	NEXTSTELLIS	DROSPIRENONE AND ESTETROL TABLETS	MAYNE PHARMA LLC	S	4/15/2021	FOR USE BY FEMALES OF REPRODUCTIVE POTENTIAL TO PREVENT PREGNANCY
NDA 215014	EMPAVELI	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	P,O	5/14/2021	TREATMENT OF ADULT PATIENTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)
NDA 214793	PYLARIFY	PIFLUFOLASTAT F-18	PROGENICS PHARMACEUTICALS INC	P	5/26/2021	FOR THE USE OF PYLARIFY (PIFLUFOLASTAT F 18 INJECTION) FOR POSITRON EMISSION TOMOGRAPHY (PET) OF PROSTATE-SPECIFIC MEMBRANE ANTIGEN (PSMA) POSITIVE LESIONS IN MEN WITH PROSTATE CANCER: • WITH SUSPECTED METASTASIS WHO ARE CANDIDATES FOR INITIAL DEFINITIVE THERAPY. • WITH SUSPECTED RECURRENCE BASED ON ELEVATED SERUM PROSTATE-SPECIFIC ANTIGEN (PSA) LEVEL.
NDA 213378	LYBALVI	OLANZAPINE AND SAMIDORPHAN	ALKERMES INC	S	5/28/2021	NDA 213378/ORIGINAL 1 – TREATMENT OF SCHIZOPHRENIA (ADULTS) NDA 213378/ORIGINAL 2 – ACUTE TREATMENT OF MANIC OR MIXED EPISODES AS MONOTHERAPY AND AS ADJUNCT TO LITHIUM OR VALPROATE ASSOCIATED WITH BIPOLAR I DISORDER AND MAINTENANCE MONOTHERAPY TREATMENT OF BIPOLAR I DISORDER (ADULTS)
NDA 214622	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC	P,O	5/28/2021	FOR THE 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 214665	LUMAKRAS	SOTORASIB	AMGEN INC	P,O	5/28/2021	FOR THE 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	BREXAFEMME	IBREXAFUNGERP	SCYNEXIS INC	P	6/1/2021	FOR THE TREATMENT OF ADULT AND POST-MENARCHAL PEDIATRIC FEMALES WITH VULVOVAGINAL CANDIDIASIS (VVC)
NDA 215341	KERENDIA	FINERENONE	BAYER HEALTHCARE PHARMACEUTICALS INC	P	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)
NDA 214429		FEXINIDAZOLE	SANOFI AVENTIS US LLC	P,O	7/16/2021	FOR THE TREATMENT OF BOTH FIRST-STAGE (HEMOLYMPHATIC) AND SECOND-STAGE (MENINGOENCEPHALITIC) HUMAN AFRICAN TRYPANOSOMIASIS (HAT) DUE TO TRYPANOSOMA BRUCEI GAMBIENSE IN PATIENTS 6 YEARS OF AGE AND OLDER AND WEIGHING AT LEAST 20 KG.
NDA 214783	REZUROCK	BELUMOSUDIL	KADMON PHARMACEUTICALS LLC	P,O	7/16/2021	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH CHRONIC GRAFT-VERSUS-HOST DISEASE (CHRONIC GVHD) AFTER FAILURE OF AT LEAST TWO PRIOR LINES OF SYSTEMIC THERAPY
NDA 215498	BYLVAY	ODEVIXIBAT	ALBIREO AB	P,O	7/20/2021	FOR THE TREATMENT OF PRURITUS IN PATIENTS 3 MONTHS OF AGE AND OLDER, WITH PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC)

NDA 215383	WELIREG	BELZUTIFAN	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P,O	8/13/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH VON HIPPEL-LINDAU (VHL) DISEASE WHO REQUIRE THERAPY FOR ASSOCIATED RENAL CELL CARCINOMA (RCC), CENTRAL NERVOUS SYSTEM (CNS) HEMANGIOBLASTOMAS, OR PANCREATIC NEUROENDOCRINE TUMORS (PNET), NOT REQUIRING IMMEDIATE SURGERY
NDA 214916	KORSUVA	DIFELIKEFALIN	CARA THERAPEUTICS INC	P	8/23/2021	A KAPPA OPIOID RECEPTOR AGONIST INDICATED FOR THE TREATMENT OF MODERATE-TO-SEVERE PRURITUS ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD-AP) IN ADULTS UNDERGOING HEMODIALYSIS (HD).
NDA 215310	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	P,O	9/15/2021	FOR THE 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 215206	QULIPTA	ATOGEPANT	ABBVIE INC	P	9/28/2021	PREVENTIVE TREATMENT OF EPISODIC MIGRAINE IN ADULTS
NDA 214662	LIVMARLI	MARALIXIBAT	MIRUM PHARMACEUTICALS INC	P,O	9/29/2021	FOR THE TREATMENT OF CHOLESTATIC PRURITUS IN PATIENTS WITH ALAGILLE SYNDROME (ALGS) 1 YEAR OF AGE AND OLDER.
NDA 214487	TAVNEOS	AVACOPAN	CHEMOCENTRYX INC	S,O	10/7/2021	ADJUNCTIVE TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY (ANCA)-ASSOCIATED VASCULITIS (GRANULOMATOSIS WITH
NDA 215358	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	P,O	10/29/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML) IN CHRONIC PHASE (CP), PREVIOUSLY
NDA 214938	VOXZOGO	VOSORITIDE	BIOMARIN PHARMACEUTICAL INC	P,O	11/19/2021	INCREASE LINEAR GROWTH IN PEDIATRIC PATIENTS WITH ACHONDROPLASIA WHO ARE 5 YEARS OF AGE AND OLDER WITH OPEN EPIPHYSES.
NDA 215596	LIVTENCITY	MARIBAVIR	TAKEDA PHARMACEUTICALS USA INC	P,O	11/23/2021	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS (12 YEARS OF AGE AND OLDER AND WEIGHING AT LEAST 35 KG) WITH POST-TRANSPLANT CMV INFECTION/DISEASE THAT
NDA 214907	CYTALUX	PAFOLACIANINE SODIUM	ON TARGET LABORATORIES INC	P,O	11/29/2021	AN OPTICAL IMAGING AGENT INDICATED IN ADULT PATIENTS WITH OVARIAN CANCER AS AN ADJUNCT FOR INTRAOPERATIVE IDENTIFICATION OF MALIGNANT LESIONS.
NDA 214012	LEQVIO	INCLISIRAN	NOVARTIS PHARMACEUTICALS CORP	S	12/22/2021	AS AN ADJUNCT TO DIET AND MAXIMALLY TOLERATED STATIN THERAPY FOR THE TREATMENT OF ADULTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH)

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761181	EVKEEZA	EVINACUMAB-DGNB	REGENERON PHARMACEUTICALS, INC.	P,O	2/11/2021	ADJUNCT TO OTHER LOW-DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C) LOWERING THERAPIES FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS, AGED 12 YEARS AND OLDER, WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)
BLA 761174	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	P	4/22/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH MISMATCH REPAIR DEFICIENT (DMMR) RECURRENT OR ADVANCED ENDOMETRIAL CANCER, AS DETERMINED BY AN FDA-APPROVED TEST, THAT HAS PROGRESSED ON OR FOLLOWING PRIOR TREATMENT WITH A PLATINUM-CONTAINING REGIMEN. THIS INDICATION IS APPROVED UNDER ACCELERATED APPROVAL BASED ON TUMOR RESPONSE RATE AND DURABILITY OF RESPONSE. CONTINUED APPROVAL FOR THIS INDICATION MAY BE CONTIGENT UPON VERIFICATION AND DESCRIPTION OF CLINICAL BENEFIT IN A CONFIRMATORY

BLA 761196	ZYNLONTA	LONCASTUXIMAB TESIRINE-LPYL	ADC THERAPEUTICS SA	P,O	4/23/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA AFTER TWO OR MORE LINES OF SYSTEMIC THERAPY, INCLUDING DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND HIGH GRADE B-CELL LYMPHOMA
BLA 761210	RYBREVANT	AMIVANTAMAB-VMJW	JANSSEN BIOTECH, INC.	P	5/21/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON SMALL CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 20 INSERTION MUTATIONS, AS DETECTED BY AN FDA APPROVED TEST, WHOSE DISEASE HAS PROGRESSED ON OR AFTER PLATINUM BASED CHEMOTHERAPY
BLA 761178	ADUHELM	ADUCANUMAB-AVWA	BIOGEN INC.	P	6/7/2021	FOR THE TREATMENT OF ALZHEIMER'S DISEASE. THIS INDICATION IS APPROVED UNDER ACCELERATED APPROVAL BASED ON REDUCTION IN AMYLOID BETA PLAQUES OBSERVED IN PATIENTS TREATED WITH ADUHELM. CONTINUED APPROVAL FOR THIS INDICATION MAY BE CONTINGENT UPON VERIFICATION OF CLINICAL BENEFIT IN CONFIRMATORY TRIAL(S)
BLA 761179	RYLAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)- RYWN	JAZZ PHARMACEUTICALS IRELAND LIMITED	S,O	6/30/2021	FOR THE 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 761123	SAPHNELO	ANIFROLUMAB-FNIA	ASTRAZENECA AB	S	7/30/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), RECEIVING STANDARD THERAPY
BLA 761194	NEXVIAZYME	AVALGLUCOSIDASE ALFA-NGPT	GENZYME CORPORATION	P,O	8/6/2021	FOR THE TREATMENT OF PATIENTS 1 YEAR OF AGE AND OLDER WITH LATE-ONSET POMPE DISEASE (LYSOSOMAL ACID ALPHA-GLUCOSIDASE [GAA] DEFICIENCY)
BLA 761177	SKYTROFA	LONAPEGSOMATROPIN-TCGD	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	S,O	8/25/2021	FOR THE TREATMENT OF PEDIATRIC PATIENTS 1 YEAR AND OLDER WHO WEIGH AT LEAST 11.5 KG AND HAVE GROWTH FAILURE DUE TO INADEQUATE SECRETION OF ENDOGENOUS GROWTH HORMONE
BLA 761208	TIVDAK	TISOTUMAB VEDOTIN-TFTV	SEAGEN INC.	P	9/20/2021	FOR THE TREATMENT OF ADULT PATIENTS WITH RECURRENT OR METASTATIC CERVICAL CANCER WITH DISEASE PROGRESSION ON OR AFTER CHEMOTHERAPY.
BLA 761166	BESREMI	ROPEGINTERFERON-ALFA-2B-NJFT	PHARMAESSENTIA CORPORATION	S,O	11/12/2021	FOR THE TREATMENT OF ADULTS WITH POLYCYTHEMIA VERA
BLA 761195	VYVGART	EFGARTIGIMOD ALFA-FCAB	ARGENX BV	S,O	12/17/2021	FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS (GMG) IN ADULT PATIENTS WHO ARE ANTI-ACETYLCHOLINE RECEPTOR (ACHR) ANTIBODY POSITIVE
BLA 761224	TEZSPIRE	TEZEPELUMAB-EKKO	ASTRAZENECA AB	P	12/17/2021	FOR THE ADD-ON MAINTENANCE TREATMENT OF ADULT AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER WITH SEVERE ASTHMA
BLA 761180	ADBRY	TRALOKINUMAB-LDRM	LEO PHARMA A/S	S	12/27/2021	FOR THE TREATMENT OF MODERATE-TO-SEVERE ATOPIC DERMATITIS IN ADULT PATIENTS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT ADVISABLE. ADBRY CAN BE USED WITH OR WITHOUT TOPICAL CORTICOSTEROIDS

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).