CY 2020 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of Decemeber 31, 2020

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

Selection Criteria:
User Response: Start Date: 1/1/2020 End Date: 12/31/2020
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 212608	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	P,O	1/9/2020	FOR THE 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 211723	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	P,O	1/23/2020	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS AGED 16 YEARS AND OLDER WITH METASTATIC OR LOCALLY ADVANCED EPITHELIOID SARCOMA NOT ELIGIBLE FOR COMPLETE RESECTION
NDA 211281	PIZENSY	LACTITOL	BRAINTREE LABORATORIES INC	S	2/12/2020	FOR THE TREATMENT OF CHRONIC IDIOPATHIC CONSTIPATION (CIC) IN ADULTS
NDA 211616	NEXLETOL	BEMPEDOIC ACID	ESPERION THERAPEUTICS INC	S	2/21/2020	FOR THE TREATMENT OF ADULTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA OR ESTABLISHED ATHEROSCLEROTIC CARDIOVASCULAR DISEASE WHO REQUIRE ADDITIONAL LOWERING OF LDL-C
NDA 209510	BARHEMSYS	AMISULPRIDE	ACACIA PHARMA LTD	S	2/26/2020	FOR THE FOLLOWING: - PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING (PONV), EITHER ALONE OR IN COMBINATION WITH AN ANTIEMETIC OF A DIFFERENT CLASS - TREATMENT OF PONV IN PATIENTS WHO HAVE RECEIVED ANTIEMETIC PROPHYLAXIS WITH AN AGENT OF A DIFFERENT CLASS OR WHO HAVE NOT RECEIVED PROPHYLAXIS
NDA 212728	NURTEC ODT	RIMEGEPANT	BIOHAVEN PHARMACEUTICAL HOLDING CO LTD	P	2/27/2020	FOR THE ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS
NDA 212801	ISTURISA	OSILODROSTAT	RECORDATI RARE DISEASES INC	S,O	3/6/2020	FOR TREATMENT OF ADULT PATIENTS WITH CUSHING'S DISEASE FOR WHOM PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE
NDA 209899	ZEPOSIA	OZANIMOD	CELGENE INTERNATIONAL II SARL	S	3/25/2020	FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSINGREMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, IN ADULTS
NDA 213756	KOSELUGO	SELUMETINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	4/10/2020	FOR THE TREATMENT OF PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER WITH NEUROFIBROMATOSIS TYPE 1 (NF1) WHO HAVE SYMPTOMATIC, INOPERABLE PLEXIFORM NEUROFIBROMAS (PN)
NDA 213411	TUKYSA	TUCATINIB	SEATTLE GENETICS INC	P,O	4/17/2020	FOR USE 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 213736	PEMAZYRE	SELUMETINIB	INCYTE CORP	P,O	4/17/2020	FOR THE TREATMENT OF ADULTS WITH PREVIOUSLY TREATED, UNRESECTABLE LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA WITH A FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) FUSION OR OTHER REARRANGEMENT AS DETECTED BY AN FDA-APPROVED TEST.
NDA 212489	ONGENTYS	OPICAPONE	NEUROCRINE BIOSCIENCES INC	S	4/24/2020	AS ADJUNCTIVE TREATMENT TO LEVODOPA/CARBIDOPA IN PATIENTS WITH PARKINSON'S DISEASE (PD) EXPERIENCING "OFF" EPISODES.
NDA 213591	TABRECTA	CAPMATINIB	NOVARTIS PHARMACEUTICAL CORP	P,O	5/6/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE A MUTATION THAT LEADS TO MESENCHYMAL-EPITHELIAL TRANSITION (MET) EXON 14 SKIPPING AS DETECTED BY AN FDA-APPROVED TEST

NDA 213246	.RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	P,O	5/8/2020	FOR THE FOLLOWING INDICATIONS: • ADULT PATIENTS WITH METASTATIC RET FUSION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC); • ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET-MUTANT MEDULLARY THYROID CANCER (MTC) WHO REQUIRE SYSTEMIC THERAPY; • ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH ADVANCED OR METASTATIC RET FUSION-POSITIVE THYROID CANCER WHO REQUIRE SYSTEMIC THERAPY AND WHO ARE RADIOACTIVE IODINE-REFRACTORY (IF RADIOACTIVE IODINE IS APPROPRIATE).
NDA 213973	QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS LLC	P,O	5/15/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH ADVANCED GASTROINTESTINAL STROMAL TUMOR (GIST) WHO HAVE RECEIVED PRIOR TREATMENT WITH 3 OR MORE KINASE INHIBITORS, INCLUDING IMATINIB
NDA 212155	CERIANNA	18F-FLUOROESTRADIOL	ZIONEXA US CORP	S	5/20/2020	FOR USE WITH POSITRON EMISSION TOMOGRAPHY (PET) IMAGING FOR DETECTION OF ESTROGEN RECEPTOR (ER)-POSITIVE LESIONS AS AN ADJUNCT TO BIOPSY IN PATIENTS WITH RECURRENT OR METASTATIC BREAST CANCER
NDA 213036		ARTESUNATE	AMIVAS LLC	P,O	5/26/2020	FOR THE USE OF ARTESUNATE FOR INJECTION FOR THE INITIAL TREATMENT OF SEVERE MALARIA IN ADULT AND PEDIATRIC PATIENTS.
NDA 212123	TAUVID	FLORTAUCIPIR F18 INJECTION	AVID RADIOPHARMACEUTICALS INC	P	5/28/2020	INDICATED FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE THE DENSITY AND DISTRIBUTION OF AGGREGATED TAU NEUROFIBRILLARY TANGLES (NFTS) IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT WHO ARE BEING EVALUATED FOR ALZHEIMER'S DISEASE (AD)
NDA 213702	ZEPZELCA	LURBINECTEDIN	JAZZ PHARMACEUTICALS IRELAND LTD	P,O	6/15/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC SMALL CELL LUNG CANCER (SCLC) WITH DISEASE PROGRESSION ON OR AFTER PRIOR PLATINUM-BASED CHEMOTHERAPY
NDA 213687	DOJOLVI	TRIHEPTANOIN	ULTRAGENYX PHARMACEUTICAL INC	S,O	6/30/2020	FOR THE TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH MOLECULARLY CONFIRMED LONG-CHAIN FATTY ACID OXIDATION DISORDERS (LC-FAOD).
NDA 212295	BYFAVO	REMIMAZOLAM	ACACIA PHARMA LTD	S	7/2/2020	FOR THE INDUCTION AND MAINTENANCE OF PROCEDURAL SEDATION IN ADULTS UNDERGOING PROCEDURES LASTING 30 MINUTES OR LESS
NDA 212950	RUKOBIA	FOSTEMSAVIR	VIIV HEALTHCARE CO	P	7/2/2020	FOR THE TREATMENT OF HIV-1 INFECTION IN HEAVILY TREATMENTEXPERIENCED ADULTS WITH MULTIDRUG-RESISTANT HIV-1 INFECTION FAILING THEIR CURRENT ANTIRETROVIRAL REGIMEN DUE TO RESISTANCE, INTOLERANCE, OR SAFETY CONSIDERATIONS
NDA 212576	INQOVI	DECITABINE AND CEDAZURIDINE	OTSUKA PHARMACEUTICAL CO LTD	P,O	7/7/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH MYELODYSPLASTIC SYNDROMES (MDS), INCLUDING PREVIOUSLY TREATED AND UNTREATED, DE NOVO AND SECONDARY MDS WITH THE FOLLOWING FRENCH-AMERICAN-BRITISH SUBTYPES (REFRACTORY ANEMIA, REFRACTORY ANEMIA WITH RINGED SIDEROBLASTS, REFRACTORY ANEMIA WITH EXCESS BLASTS, AND CHRONIC MYELOMONOCYTIC LEUKEMIA [CMML]) AND INTERMEDIATE-1, INTERMEDIATE-2, AND HIGH-RISK INTERNATIONAL PROGNOSTIC SCORING SYSTEM GROUPS
NDA 206966	XEGLYZE	ABAMETAPIR	DR REDDYS LABORATORIES SA	S	7/24/2020	FOR THE TREATMENT OF HEAD LICE INFESTATION IN PATIENTS 6 MONTHS OF AGE AND OLDER
NDA 213464	LAMPIT	NIFURTIMOX	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	8/6/2020	FOR THE TREATMENT OF CHAGAS DISEASE IN PEDIATRIC PATIENTS BIRTH TO LESS THAN 18 YEARS OF AGE AND WEIGHING AT LEAST 2.5 KG
NDA 210730	OLINVYK	OLICERIDINE	TREVENA INC	S	8/7/2020	FOR THE MANAGEMENT OF ACUTE PAIN SEVERE ENOUGH TO REQUIRE AN INTRAVENOUS OPIOID ANALGESIC AND FOR WHOM ALTERNATIVE TREATMENTS ARE INADEQUATE
NDA 213535	EVRYSDI	RISDIPLAM	GENENTECH INC	P,O	8/7/2020	FOR THE TREATMENT OF SPINAL MUSCULAR ATROPHY (SMA) IN PATIENTS 2 MONTHS OF AGE AND OLDER
NDA 212154	VILTEPSO	VILTOLARSEN	NIPPON SHINYAKU CO LTD	P,O	8/12/2020	FOR THE 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 213433	WINLEVI	CLASCOTERONE	CASSIOPEA SPA	S	8/26/2020	FOR THE TOPICAL TREATMENT OF ACNE VULGARIS IN PATIENTS 12 YEARS OF AGE AND OLDER
NDA 213227	DETECTNET	COPPER CU 64 DOTATATE INJECTION	RADIOMEDIX INC	P,O	9/3/2020	AS A RADIOACTIVE DIAGNOSTIC AGENT INDICATED FOR USE WITH POSITRON EMISSION TOMOGRAPHY (PET) FOR LOCALIZATION OF SOMATOSTATIN RECEPTOR POSITIVE NEUROENDOCRINE TUMORS (NETS) IN ADULTS

NDA 213721	GAVRETO	PRALSETINIB	BLUEPRINT MEDICINES CORP	P,O	9/4/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC RET FUSION-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC) AS DETECTED BY AN FDA APPROVED TEST
NDA 214787	VEKLURY	REMDESIVIR	GILEAD SCIENCES INC	P	10/22/2020	FOR THE TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19) REQUIRING HOSPITALIZATION. VEKLURY SHOULD ONLY BE ADMINISTERED IN A HOSPITAL OR IN A HEALTHCARE SETTING CAPABLE OF PROVIDING ACUTE CARE COMPARABLE TO INPATIENT HOSPITAL CARE
NDA 213969	ZOKINVY	LONAFARNIB	EIGER BIOPHARMACEUTICALS INC	P,O	11/20/2020	TO REDUCE THE RISK OF MORTALITY IN HUTCHINSON-GILFORD PROGERIA SYNDROME (HGPS) • FOR THE TREATMENT OF PROCESSING-DEFICIENT PROGEROID LAMINOPATHIES WITH EITHER: • HETEROZYGOUS LMNA MUTATION WITH PROGERIN-LIKE PROTEIN ACCUMULATION O HOMOZYGOUS OR COMPOUND HETEROZYGOUS ZMPSTE24 MUTATIONS
NDA 214103	OXLUMO	LUMASIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	11/23/2020	FOR THE TREATMENT OF PRIMARY HYPEROXALURIA TYPE 1 (PH1) TO LOWER URINARY OXALATE LEVELS IN PEDIATRIC AND ADULT PATIENTS
NDA 213793	IMCIVREE	SETMELANOTIDE	RHYTHM PHARMACEUTICALS INC	P,O	11/25/2020	FOR CHRONIC WEIGHT MANAGEMENT IN ADULT AND PEDIATRIC PATIENTS 6 YEARS OF AGE AND OLDER WITH OBESITY DUE TO PROOPIOMELANOCORTIN (POMC), PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 1 (PCSK1), OR LEPTIN RECEPTOR (LEPR) DEFICIENCY CONFIRMED BY GENETIC TESTING DEMONSTRATING VARIANTS IN POMC, PCSK1, OR LEPR GENES THAT ARE INTERPRETED AS PATHOGENIC, LIKELY PATHOGENIC, OR OF UNCERTAIN SIGNIFICANCE (VUS)
NDA 212642		PSMA-11 GA 68	UNIV CALIFORNIA LOS ANGELES	S	12/1/2020	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 214094	ORLADEYO	BEROTRALSTAT	BIOCRYST PHARMACEUTICALS INC	S,O	12/3/2020	S FOR PROPHYLAXIS TO PREVENT ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS AND OLDER
NDA 213189	KLISYRI	TIRBANIBULIN	ALMIRALL LLC	S	12/14/2020	FOR THE TOPICAL TREATMENT OF ACTINIC KERATOSIS ON THE FACE OR SCALP
NDA 214621	ORGOVYX	RELUGOLIX	MYOVANT SCIENCES GMBH	P	12/18/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH ADVANCED PROSTATE CANCER.
NDA 213006	GEMTESA	VIBEGRON	UROVANT SCIENCES GMBH	S	12/23/2020	TREATMENT OF OVERACTIVE BLADDER WITH SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY, AND URINARY FREQUENCY IN ADULTS.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761143	TEPEZZA	TEPROTUMUMAB-TRBW	HORIZON THERAPEUTICS IRELAND DAC	P,O	1/21/2020	FOR THE TREATMENT OF THYROID EYE DISEASE
BLA 761119	VYEPTI	EPTINEZUMAB-JJMR	LUNDBECK SEATTLE BIOPHARMACEUTICALS, INC.	S	2/21/2020	PREVENTIVE TREATMENT OF MIGRAINE IN ADULTS
BLA 761113	SARCLISA	ISATUXIMAB-IRFC	SANOFI-AVENTIS U.S. LLC	S,O	3/2/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND A PROTEASOME INHIBITOR
BLA 761115	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS, INC.	P	4/22/2020	FOR THE TREATMENT OF ADULT PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER (MTNBC) WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES FOR METASTATIC DISEASE
BLA 761142	UPLIZNA	INEBILIZUMAB-CDON	VIELA BIO	S,O	6/11/2020	FOR FOR THE TREATMENT OF NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) IN ADULT PATIENTS WHO ARE ANTI-AQUAPORIN-4 (AQP4) ANTIBODY POSITIVE

BLA 761163	MONJUVI	TAFASITAMAB-CXIX	MORPHOSYS US INC.	P,O	7/31/2020	IN COMBINATION WITH LENALIDOMIDE FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOTOTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND WHO ARE NOT ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT (ASCT)
BLA 761158	BLENREP	BELANTAMAB MAFODOTIN-BLMF	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD. ENGLAND	P,O	8/5/2020	FOR THE TREATMENT OF ADULTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST FOUR PRIOR THERAPIES INCLUDING AN ANTI-CD38 MONOCLONAL ANTIBODY, A PROTEASOME INHIBITOR, AND AN IMMUNOMODULATORY AGENT
BLA 761149	ENSPRYNG	SATRALIZUMAB-MWGE	GENENTECH, INC.	S,O	8/14/2020	FOR THE TREATMENT OF NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) IN ADULT PATIENTS WHO ARE ANTI-AQUAPORIN-4 (AQP4) ANTIBODY POSITIVE
BLA 761156	SOGROYA	SOMAPACITAN-BECO	NOVO NORDISK INC.	S	8/28/2020	FOR REPLACEMENT OF ENDOGENOUS GROWTH HORMONE IN ADULTS WITH GROWTH HORMONE DEFICIENCY.
BLA 761169	INMAZEB	ATOLTIVIMAB, MAFTIVIMAB, AND ODESIVIMAB-EBGN	REGENERON PHARMACEUTICALS, INC.	P,O	10/14/2020	FOR THE TREATMENT OF INFECTION CAUSED BY ZAIRE EBOLAVIRUS IN ADULT AND PEDIATRIC PATIENTS, INCLUDING NEONATES BORN TO A MOTHER WHO IS RT-PCR POSITIVE FOR ZAIRE EBOLAVIRUS INFECTION
BLA 761171	DANYELZA	NAXITAMAB-GQGK	Y-MABS THERAPEUTICS, INC.	P,O	11/25/2020	IN COMBINATION WITH GRANULOCYTEMACROPHAGE COLONY-STIMULATING FACTOR (GM-CSF), FOR THE TREATMENT OF PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER AND ADULT PATIENTS WITH RELAPSED OR REFRACTORY HIGH-RISK NEUROBLASTOMA IN THE BONE OR BONE MARROW WHO HAVE DEMONSTRATED A PARTIAL RESPONSE, MINOR RESPONSE, OR STABLE DISEASE TO PRIOR THERAPY
BLA 761150	MARGENZA	MARGETUXIMAB-CMKB	MACROGENICS INC.	S	12/16/2020	FOR THE 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
BLA 761172	EBANGA	ANSUVIMAB-ZYKL	RIDGEBACK BIOTHERAPEUTICS	P,O	12/21/2020	FOR THE TREATMENT OF INFECTION CAUSED BY ZAIRE EBOLAVIRUS IN ADULT AND PEDIATRIC PATIENTS, INCLUDING NEONATES BORN TO A MOTHER WHO IS RT-PCR POSITIVE FOR ZAIRE EBOLAVIRUS INFECTION

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).