

CY 2020 Fast Track Calendar Year Approvals*

Data as of 31-Dec-2020/Revised 23-Dec-2021

Total of 35 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	USE
BLA 761150	ORIG - 1	MARGENZA	MARGETUXIMAB - CMKB	MACROGENICS INC	16-Dec-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	03-Dec-2020	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
NDA 214787	ORIG - 1	VEKLURY	REMEDSIVIR	GILEAD SCIENCES INC	22-Oct-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	13-Oct-2020	Treatment of cataplexy in adult patients with narcolepsy
BLA 125526	SUPPL - 17	NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE LLC	25-Sep-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	25-Sep-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	03-Sep-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	14-Aug-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	12-Aug-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	07-Aug-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	07-Aug-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	31-Jul-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	31-Jul-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	02-Jul-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	02-Jul-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	30-Jun-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	25-Jun-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	22-Jun-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	18-Jun-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	04-Jun-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	27-May-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	26-May-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	26-May-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	26-May-2020	Initial treatment of severe malaria in adult and pediatric patients
NDA 213973	ORIG - 1	QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS LLC	15-May-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	05-May-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	22-Apr-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	17-Apr-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	15-Apr-2020	Treatment of adult patients with low-grade upper tract urothelial cancer
BLA 761136	ORIG - 2	REBLOZYL	LUSPATERCEPT AAMT	CELGENE CORPORATION	03-Apr-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	19-Mar-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	24-Jan-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	HORIZON THERAPEUTICS IRELAND DAC	21-Jan-2020	Treatment of thyroid eye disease
NDA 211635	ORIG - 1	VALTOCO	DIAZEPAM	NEURELIS INC	10-Jan-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	09-Jan-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

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