

## CY 2020 CDER Fast Track Calendar Year Approvals\*

Data as of 30 June 2020

Total of 20 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	USE
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
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
BLA 761143	ORIG - 1	TEPEZZA	TEPROTUMUMAB-TRBW	HORIZON THERAPEUTICS IRELAND DAC	21-Jan-2020	Treatment of thyroid eye disease
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
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

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/myeloproliiferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
NDA 211728	ORIG - 1	JELMYTO	MITOMYCIN	UROGEN PHARMA LTD	15-Apr-2020	Treatment of adult patients with low-grade upper tract urothelial cancer
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
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 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
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

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
NDA 213036	ORIG - 1	NA	ARTESUNATE FOR INJECTION	AMIVAS LLC	26-May-2020	Initial treatment of severe malaria in adult and pediatric patients
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 $\geq$ 5 to <12 years of age and weighing at least 15 kg
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 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 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 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 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)
<b>NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded.</b>						