# CY 2021 CDER Fast Track Calendar Year Approvals*

***Data as of 30 June 2021***

***Total of 20 Approvals***

| Appl Type Number | Submission Type and Number | Propriety Name | Established Name | Applicant | Approval Date | Use |
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| NDA 214377 | ORIG - 1 | VERQUVO | VERICIGUAT | MERCK SHARP AND DOHME CORP | 19-Jan-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 212887 | ORIG - 1 | VOCABRIA | CABOTEGRAVIR TABLETS | VIIV HEALTHCARE CO | 21-Jan-2021 | In combination with Edurant (rilpivirine) 25 mg tablet for the short-term treatment of HIV1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpirivine release injectable suspension) |

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| NDA 212888 | ORIG - 1 | CABENUVA | CABOTEGRAVIR AND RILPIVIRINE - EXTENDED RELEASE INJECTABLE SUSPENSION | VIIV HEALTHCARE CO | 21-Jan-2021 | 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 |
| BLA 125554 | SUPPL - 90 | OPDIVO | NIVOLUMAB | BRISTOL-MYERS SQUIBB COMPANY | 22-Jan-2021 | Treatment of patients with advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib |
| NDA 213716 | ORIG - 1 | LUPKYNIS | VOCLOSPORIN | AURINIA PHARMACEUTICALS INC | 22-Jan-2021 | In combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis |
| NDA 213026 | ORIG - 1 | AMONDYS 45 | CASIMERSEN | SAREPTA THERAPEUTICS INC | 25-Feb-2021 | Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping |
| BLA 761115 | SUPPL - 9 | TRODELVY | SACITUZUMAB GOVITECAN-HZIY | IMMUNOMEDICS INC | 13-Apr-2021 | Treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed deathligand 1 (PD-L1) inhibitor |

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| NDA 021825 | SUPPL - 8 | FERRIPROX | DEFERIPRONE | CHIESI USA INC | 30-Apr-2021 | Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias |
| NDA 202293 | SUPPL - 24 | FARXIGA | DAPAGLIFLOZIN | ASTRAZENECA AB | 30-Apr-2021 | To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression |
| NDA 208030 | SUPPL - 5 | FERRIPROX | DEFERIPRONE ORAL SOLUTION | CHIESI USA INC | 30-Apr-2021 | Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias |
| NDA 212269 | SUPPL - 1 | FERRIPROX | DEFERIPRONE TABLETS | CHIESI USA INC | 30-Apr-2021 | Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias |
| NDA 211988 | ORIG - 1 | ZYNRELEF | BUPIVACAINE AND MELOXICAM | HERON THERAPEUTICS INC | 12-May-2021 | For soft tissue or periarticular instillation use to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty |
| NDA 215014 | ORIG - 1 | EMPAVELI | PEGCETACOPLAN | APELLIS PHARMACEUTICALS INC | 14-May-2021 | Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) |

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| NDA 214622 | ORIG - 1 | TRUSELTIQ | INFIGRATINIB | QED THERAPEUTICS INC | 28-May-2021 | 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 | ORIG - 1 | LUMAKRAS | SOTORASIB | AMGEN INC | 28-May-2021 | 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 | ORIG - 1 | BREXAFEMME | IBREXAFUNGERP | SCYNEXIS INC | 01-Jun-2021 | Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis |
| NDA 214460 | ORIG - 1 | TEMBEXA ORAL SUSPENSION | BRINCIDOFOVIR | CHIMERIX INC | 04-Jun-2021 | Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates |
| NDA 214461 | ORIG - 1 | TEMBEXA TABLETS | BRINCIDOFOVIR | CHIMERIX INC | 04-Jun-2021 | Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates |
| BLA 761178 | ORIG - 1 | ADUHELM | ADUCANUMAB-AVWA | BIOGEN INC | 07-Jun-2021 | Treatment of Alzheimer's disease |

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| BLA 761179 | ORIG - 1 | RYLAZE | ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)-RYWN | JAZZ PHARMACEUTICALS IRELAND LIMITED | 30-Jun-2021 | 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 |

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