CY 2023 CDER Breakthrough Therapy Calendar Year Approvals

Data as of September 30, 2023
Total of 13 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
BLA 761269	ORIGINAL-1	LEQEMBI	LECANEMAB-IRMB	EISAI INC	06-Jan-2023	Treatment of Alzheimer's disease
NDA 213411	SUPPLEMENT-4	TUKYSA	TUCATINIB	SEAGEN INC	19-Jan-2023	In combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
BLA 761164	SUPPLEMENT-3	ENJAYMO	SUTIMLIMAB-JOME	BIOVERATIV USA INC	25-Jan-2023	Treatment of hemolysis in adults with cold agglutinin disease (CAD)
NDA 217514	ORIGINAL-1	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	16-Mar-2023	In combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy
BLA 125514	SUPPLEMENT-136	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME LLC	03-Apr-2023	In combination with enfortumab vedotin for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy
BLA 761137	SUPPLEMENT-18	PADCEV	ENFORTUMAB VEDOTIN-EJFV	ASTELLAS PHARMA US INC	03-Apr-2023	In combination with pembrolizumabfor the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin-containing chemotherapy
BLA 761174	SUPPLEMENT-6	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	31-Jul-2023	In combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA approved test, or microsatellite instability-high (MSI-H)
NDA 217225	ORIGINAL-1	IZERVAY	AVACINCAPTAD PEGOL	IVERIC BIO INC	04-Aug-2023	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

BLA 761342	ORIGINAL-1	TALVEY	TALQUETAMAB-TGVS	JANSSEN BIOTECH INC	09-Aug-2023	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody
BLA 761345	ORIGINAL-1	ELREXFIO	ELRANATAMAB-BCMM	PFIZER INC	14-Aug-2023	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
BLA 761204	ORIGINAL-1	POMBILITI	CIPAGLUCOSIDASE ALFA-ATGA	AMICUS THERAPEUTICS US LLC	28-Sep-2023	In combination with Opfolda, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT)
NDA 215211	ORIGINAL-1	OPFOLDA	MIGLUSTAT	AMICUS THERAPEUTICS US LLC	28-Sep-2023	In combination with Pombiliti, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT)
NDA 215842	ORIGINAL-1	RIVFLOZA	NEDOSIRAN	NOVO NORDISK INC	29-Sep-2023	To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2