

CY 2021 CDER Breakthrough Therapy Calendar Year Approvals

Data as of September 30, 2021

Total of 23 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 202570	SUPPLEMENT-30	XALKORI	CRIZOTINIB	PF PRISM CV	14-Jan-2021	Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK positive
BLA 761139	SUPPLEMENT-11	ENHERTU	FAM- TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	15-Jan-2021	Treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen
NDA 213176	ORIGINAL-1	UKONIQ	UMBRALISIB	TG THERAPEUTICS INC	05-Feb-2021	Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen
BLA 761181	ORIGINAL-1	EVKEEZA	EVINACUMAB- DGNB	REGENERON PHARMACEUTICALS INC	11-Feb-2021	As an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH)
NDA 214200	ORIGINAL-1	COSELA	TRILACICLIB	G1 THERAPEUTICS INC	12-Feb-2021	To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan containing regimen for extensive-stage small cell lung cancer
NDA 214018	ORIGINAL-1	NULIBRY	FOSDENOPTERIN	ORIGIN BIOSCIENCES INC	26-Feb-2021	To reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A

BLA 125472	SUPPLEMENT-44	ACTEMRA	TOCILIZUMAB	GENENTECH INC	04-Mar-2021	For slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)
BLA 125249	SUPPLEMENT-49	ARCALYST	RILONACEPT	KINIKSA PHARMACEUTICALS (UK) LTD	18-Mar-2021	Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older
BLA 761174	ORIGINAL-1	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	22-Apr-2021	Treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen
NDA 202293	SUPPLEMENT-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 211988	ORIGINAL-1	ZYNRELEF	BUPIVACAINE AND MELOXICAM	HERON THERAPEUTICS INC	12-May-2021	For use in adults 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
BLA 761210	ORIGINAL-1	RYBREVANT	AMIVANTAMAB-VMJW	JANSSEN BIOTECH INC	21-May-2021	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy
NDA 214665	ORIGINAL-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 212608	SUPPLEMENT-6	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	16-Jun-2021	Treatment of adult patients with advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis (ASM) and systemic mastocytosis with an associated hematological neoplasm (SM-AHN)
NDA 212608	SUPPLEMENT-7	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	16-Jun-2021	Treatment of adult patients with mast cell leukemia (MCL)
NDA 214783	ORIGINAL-1	REZUROCK	BELUMOSUDIL	KADMON PHARMACEUTICALS	16-Jul-2021	Treatment of adult and pediatric patients 12 years and older with chronic graft versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy
BLA 125514	SUPPLEMENT-89	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP	26-Jul-2021	Treatment of patients with high-risk, early-stage triple negative breast cancer, in combination with chemotherapy as neoadjuvant treatment, then as a single agent as adjuvant treatment after surgery
BLA 761194	ORIGINAL-1	NEXVIAZYME	AVALGLUCOSIDASE ALFA-NGPT	GENZYME CORPORATION	06-Aug-2021	Treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)
NDA 206947	SUPPLEMENT-19	LENVIMA	LENVATINIB	EISAI INC	10-Aug-2021	In combination with pembrolizumab for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)
NDA 214916	ORIGINAL-1	KORSUVA	DIFELIKEFALIN	CARA THERAPEUTICS INC	23-Aug-2021	Treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD)
NDA 215310	ORIGINAL-1	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	15-Sep-2021	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy

NDA 208692	SUPPLEMENT-12	CABOMETYX	CABOZANTINIB	EXELIXIS INC	17-Sep-2021	Treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
NDA 214662	ORIGINAL-1	LIVMARLI	MARALIXIBAT	MIRUM PHARMACEUTICALS INC	29-Sep-2021	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older