

CDER Breakthrough Therapy Designation Approvals

Data as of December 31, 2025

Total of 37 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 214665	SUPPLEMENT-9	LUMAKRAS	SOTORASIB	AMGEN INC	16-Jan-2025	In combination with panitumumab, for the treatment of adult patients with KRAS G12C-mutated metastatic colorectal cancer as determined by an FDA approved test, who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
NDA 211243	SUPPLEMENT-16	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	17-Jan-2025	For treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant
BLA 761139	SUPPLEMENT-32	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	27-Jan-2025	The treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one or more endocrine therapies in the metastatic setting
NDA 219209	ORIGINAL-1	JOURNAVX	SUZETRIGINE (VX-548)	VERTEX PHARMACEUTICALS INC	30-Jan-2025	The treatment of moderate to severe acute pain in adults
NDA 218276	SUPPLEMENT-4	FABHALTA	IPTACOPAN	NOVARTIS PHARMACEUTICALS CORP	20-Mar-2025	The treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria
NDA 216665	ORIGINAL-1	VYKAT XR	DIAZOXIDE CHOLINE	SOLENO THERAPEUTICS INC	26-Mar-2025	The treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome
BLA 761142	SUPPLEMENT-3	UPLIZNA	INEBILIZUMAB	HORIZON THERAPEUTICS IRELAND DAC	03-Apr-2025	For use of in adult patients with immunoglobulin G4- Related Disease (IgG4-RD)
BLA 125377	SUPPLEMENT-135	YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB COMPANY	08-Apr-2025	In combination with nivolumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC)
BLA 125554	SUPPLEMENT-132	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	08-Apr-2025	In combination with ipilimumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC)
BLA 761258	ORIGINAL-1		PENPULIMAB-KCQX	AKESO BIOPHARMA CO LTD	23-Apr-2025	Penpulimab-kcqx is indicated: <ul style="list-style-type: none"> • In combination with either cisplatin or carboplatin and gemcitabine, for the firstline treatment of adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) • As a single agent, for the treatment of adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy
NDA 219616	ORIGINAL-1	AVMAPKI FAKZYNJA CO-PACK	AVUTOMETINIB	VERASTEM INC	08-May-2025	The treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy
BLA 761384	ORIGINAL-1	EMRELIS	TELISOTUZUMAB VEDOTIN-TLLV	ABBVIE INC	14-May-2025	The treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [=50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy

NDA 209394	SUPPLEMENT-19	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	10-Jun-2025	The treatment of acute hepatitis C virus (HCV) infection in adults and pediatric patients ages 3 to less than 18 years of age
NDA 215110	SUPPLEMENT-5	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	10-Jun-2025	The treatment of acute hepatitis C virus (HCV) infection in adults and pediatric patients ages 3 to less than 18 years of age
NDA 219713	ORIGINAL-1	IBTROZI	TALETRECTINIB	NUVATION BIO INC	11-Jun-2025	The treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)
NDA 220018	ORIGINAL-1	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	18-Jun-2025	Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition
NDA 220020	ORIGINAL-1	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	18-Jun-2025	Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition
BLA 761464	ORIGINAL-1	DATROWAY	DATOPOTAMAB DERUXTECAN-DLNC	DAIICHI SANKYO INC	23-Jun-2025	The treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based therapy
NDA 219839	ORIGINAL-1	ZEGFROVY	SUNVOZERTINIB	DIZAL (JIANGSU) PHARMACEUTICAL CO LTD	02-Jul-2025	The 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 219042	ORIGINAL-1	HERNEXEOS	ZONGERTINIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	08-Aug-2025	Treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy
NDA 217673	ORIGINAL-1	BRINSUPRI	BRENSOCATIB	INSMED INC	12-Aug-2025	The treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older
NDA 215256	SUPPLEMENT-24	WEGOVI	SEMAGLUTIDE	NOVO NORDISK INC	15-Aug-2025	For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults
NDA 219683	ORIGINAL-1	INLEXZO	GEMCITABINE-RELEASING INTRAVESICAL SYSTEM	JANSSEN BIOTECH INC	09-Sep-2025	Treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (HR-NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
BLA 761181	SUPPLEMENT-2	EVKEEZA	EVINACUMAB	REGENERON PHARMACEUTICALS INC	25-Sep-2025	As an adjunct to diet and exercise and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies to reduce LDL-C in adults and pediatric patients, aged 1 year and older, with homozygous familial hypercholesterolemia (HoFH)
NDA 218764	ORIGINAL-1	JASCAYD	NERANDOMILAST	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	07-Oct-2025	The treatment of idiopathic pulmonary fibrosis in adult patients
BLA 125486	SUPPLEMENT-37	GAZYVA	OBINUTUZUMAB	GENENTECH INC	17-Oct-2025	Treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy A short duration infusion of approximately 90 minutes from the second infusion onwards in patients with active lupus nephritis (LN) who have completed the first obinutuzumab administration at the standard infusion rate without experiencing any Grade = 3 infusion-related reactions (IRRs)
NDA 219792	ORIGINAL-1	KYGEVVI	DOXECITINE AND DOXRIBTIMINE	UCB INC	03-Nov-2025	Treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with an age of symptom onset on or before 12 years

NDA 220305	ORIGINAL-1	KOMZIFTI	ZIFTOMENIB	KURA ONCOLOGY INC	13-Nov-2025	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options
BLA 761324	SUPPLEMENT-9	EPKINLY	EPCORITAMAB-BYSP	GENMAB US, INC.	18-Nov-2025	In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL)
NDA 219947	ORIGINAL-1	REDEMPLO	PLOZASIRAN	ARROWHEAD PHARMACEUTICALS INC	18-Nov-2025	As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)
NDA 219972	ORIGINAL-1	HYRNUO	SEVABERTINIB	BAYER HEALTHCARE PHARMACEUTICALS INC	19-Nov-2025	Treatment of adult patients with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy
BLA 761069	SUPPLEMENT-52	IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	25-Nov-2025	In combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)
BLA 761434	ORIGINAL-1	VOYXACT	SIBEPRENILIMAB-SZSI	OTSUKA PHARMACEUTICAL COMPANY LTD	25-Nov-2025	To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression
BLA-761139	SUPPLEMENT-38	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO, INC.	15-Dec-2025	In combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined by an FDA-approved test
NDA 219083	ORIGINAL-1	MYQORZO	AFICAMTEN	CYTOKINETICS INC	19-Dec-2025	The treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms
NDA 220449	ORIGINAL-1	JASCAYD	NERANDOMILAST	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	19-Dec-2025	The treatment of progressive pulmonary fibrosis in adult patients
BLA 761152	ORIGINAL-1	YARTEMLA	NARSOPLIMAB-WUUG	OMEROS CORPORATION	23-Dec-2025	Treatment of adult and pediatric patients two years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)