CY 2026 CDER Breakthrough Therapy Calendar Year Approvals

Data as of September 30, 2026

Total of 27 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 211241	ORIGINAL-1	ZYCUBO	COPPER HISTIDINATE	SENTYNL THERAPEUTICS INC	12-Jan-2026	The treatment of Menkes disease in pediatric patients
BLA 761211	ORIGINAL-1	LOARGYS	PEGZILARGINASE-NBLN	IMMEDICA PHARMA AB	23-Feb-2026	The treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction
NDA 219042	SUPPLEMENT-1	HERNEXEOS	ZONGERTINIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	26-Feb-2026	The 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-authorized test
BLA 761291	SUPPLEMENT-18	TECVAYLI	TECLISTAMAB-CQYV	JANSSEN BIOTECH INC	05-Mar-2026	The treatment of adult patients with relapsed or refractory multiple myeloma: • Conversion from accelerated approval to traditional approval for teclistamab as monotherapy, in 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 • New indication of teclistamab in combination with daratumumab hyaluronidase-fihj for the treatment of adult patients with relapsed or refractory multiple myeloma
NDA 213793	SUPPLEMENT-9	IMCIVREE	SETMELANOTIDE	RHYTHM PHARMACEUTICALS INC	19-Mar-2026	To reduce excess body weight and maintain reduction long term in adults and pediatricpatients aged: • 4 years and older with acquired hypothalamic obesity (HO) • 2 years and older with Bardet-Biedl syndrome (BBS) • 2 years and older with pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
BLA 761485	ORIGINAL-1	AVLAYAH	TIVIDENOFUSP ALFA-EKNM	DENALI THERAPEUTICS INC	24-Mar-2026	The treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment

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NDA 215430	SUPPLEMENT-18	AUVELITY	DEXTROMETHORPHAN HYDROBROMIDE AND BUPROPION HYDROCHLORIDE	AXSOME THERAPEUTICS INC	30-Apr-2026	The treatment of agitation associated with dementia due to Alzheimer's disease
BLA 761352	SUPPLEMENT-10	BIZENGRI	ZENOCUTUZUMAB-ZBCO	PARTNER THERAPEUTICS INC	08-May-2026	For treatment of patients with advanced unresectable or metastatic NRG1+ CCA
NDA 220711	ORIGINAL-1	BEQALZI	SONROTOCLAX	BEONE MEDICINES USA INC	13-May-2026	For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.
BLA 761139	SUPPLEMENT-43	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO INC	15-May-2026	ENHERTU followed by a taxane, trastuzumab, and pertuzumab (THP) is indicated for the neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer as determined by an FDA-authorized test; and ENHERTU is indicated for the adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment
BLA 761468	ORIGINAL-1	HEPCLUDEX	BULEVIRTIDE-GMOD	GILEAD SCIENCES INC	22-May-2026	Treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis
NDA 207103	SUPPLEMENT-24	IBRANCE	PALBOCICLIB	PFIZER INC	24-Jun-2026	Palbociclib is indicated in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment
NDA 212436	SUPPLEMENT-12	IBRANCE	PALBOCICLIB	PFIZER INC	24-Jun-2026	Palbociclib is indicated in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment
NDA 218614	SUPPLEMENT-4	TRYNGOLZA	OLEZARSEN	IONIS PHARMACEUTICALS INC	24-Jun-2026	To reduce TG and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG: TG greater than or equal to 500 mg/dL)
BLA 761530	ORIGINAL-1	LUMVOA	VELIGROTUG	VIRIDIAN THERAPEUTICS INC	26-Jun-2026	For the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration
BLA 761486	ORIGINAL-1	TRUTAKNA	ATACICEPT-VYMJ	VERA THERAPEUTICS INC	07-Jul-2026	To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression

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NDA 219908	ORIGINAL-1	REVTORPYK	GEDATOLISIB	CELCUITY INC	14-Jul-2026	Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a detectable PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting
NDA 221075	ORIGINAL-1	ZENBEXUS	IBERDOMIDE	BRISTOL MYERS SQUIBB CO	13-Aug-2026	In combination with daratumumab and hyaluronidase-fihj and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent
BLA 761508	ORIGINAL-1	PASATRU	GARETOSMAB-GRTS	REGENERON PHARMACEUTICALS, INC.	19-Aug-2026	An activin signaling inhibitor indicated to reduce formation of new heterotopic ossification (HO) lesions and clinician-assessed flare-ups in adults with fibrodysplasia ossificans progressiva (FOP)
BLA 761416	SUPPLEMENT-2	ZIIHERA	ZANIDATAMAB-HRII	JAZZ PHARMACEUTICALS IRELAND LIMITED	25-Aug-2026	Gastroesophageal adenocarcinoma (GEA): • In combination with fluoropyrimidine- and platinum-containing chemotherapy and tislelizumab-jsgr, as first-line treatment of adult patients with HER2-positive (IHC 3+ or IHC2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma, as detected by an FDA-authorized test • In combination with fluoropyrimidine- and platinum-containing chemotherapy, as first-line treatment of adult patients with HER2-positive (IHC 3+) unresectable locally advanced
NDA 220910	ORIGINAL-1	RASONQUE	DARAXONRASIB	REVOLUTION MEDICINES INC	26-Aug-2026	the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy
NDA 220605	ORIGINAL-1	MIMRYLO	RUSFERTIDE	TAKEDA PHARMACEUTICALS AMERICA INC	28-Aug-2026	treatment of erythrocytosis in adults with polycythemia vera (PV)
NDA 220210	ORIGINAL-1	ZANVASTRO	ZILGANERSEN	IONIS PHARMACEUTICALS INC	03-Sep-2026	for the treatment of Alexander disease in pediatric and adult patients
NDA 220359	ORIGINAL-1	ETCAMAH	CAMIZESTRANT	ASTRAZENECA PHARMACEUTICALS LP	04-Sep-2026	In combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon detection of ESR1 mutation during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test

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NDA 220425	ORIGINAL-1	LYRFIGTU	LIRAFUGRATINIB	ELEVAR THERAPEUTICS INC	23-Sep-2026	For the treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma harboring a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement
BLA 125486	SUPPLEMENT-43	GAZYVA	OBINUTUZUMAB	GENENTECH INC	25-Sep-2026	to reduce the risk of relapse in adult and pediatric patients 2 years of age and older with frequently relapsing or steroid dependent childhood-onset idiopathic nephrotic syndrome who are in complete remission
NDA 220963	ORIGINAL-1	EMCITATE	TIRATRICOL	RARE THYROID THERAPEUTICS INTERNATIONAL AB	28-Sep-2026	For the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome)