CY 2025 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2025

This report reflects the data shown as it is identified in the database.

Selection Criteria:
User Response: Start Date: 1/1/2025 End Date: 12/31/2025
Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 214759	GRAFAPEX	TREOSULFAN	MEDEXUS PHARMA INC	S,O	1/21/2025	FOR INTRAVENOUS USE FOR: - USE IN COMBINATION WITH FLUDARABINE AS A PREPARATIVE REGIMEN FOR ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION IN ADULT AND PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER WITH ACUTE MYELOID LEUKEMIA (AML). - USE IN COMBINATION WITH FLUDARABINE AS A PREPARATIVE REGIMEN FOR ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION IN ADULT AND PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER WITH MYELODYSPLASTIC SYNDROME (MDS)
NDA 219209	JOURNAVX	SUZETRIGINE	VERTEX PHARMACEUTICALS INC	P	1/30/2025	FOR THE TREATMENT OF MODERATE TO SEVERE ACUTE PAIN IN ADULTS
NDA 219379	GOMEKLI	MIRDAMETINIB	SPRINGWORKS THERAPEUTICS INC	P,O	2/11/2025	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER WITH NEUROFIBROMATOSIS TYPE 1 (NF1) WHO HAVE SYMPTOMATIC PLEXIFORM NEUROFIBROMAS (PN) NOT AMENABLE TO COMPLETE RESECTION
NDA 219304	ROMVIMZA	VIMSELTINIB	DECIPHERA PHARMACEUTICALS LLC	P	2/14/2025	FOR THE TREATMENT OF ADULT PATIENTS WITH SYMPTOMATIC TENOSYNOVIAL GIANT CELL TUMOR (TGCT) FOR WHICH SURGICAL RESECTION WILL POTENTIALLY CAUSE WORSENING FUNCTIONAL LIMITATION OR SEVERE MORBIDITY
NDA 218230	BLUJEPA	GEPOTIDACIN	GLAXOSMITHKLINE LLC	P	3/25/2025	FOR THE TREATMENT OF FEMALE ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WEIGHING AT LEAST 40 KILOGRAMS (KG) WITH UNCOMPLICATED URINARY TRACT INFECTIONS (UUTI) CAUSED BY THE FOLLOWING SUSCEPTIBLE MICROORGANISMS: ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, CITROBACTER FREUNDII COMPLEX, STAPHYLOCOCCUS SAPROPHYTICUS, AND ENTEROCOCCUS FAECALIS
NDA 219019	QFITLIA	FITUSIRAN	GENZYME CORP	S,O	3/28/2025	FOR ROUTINE PROPHYLAXIS TO PREVENT OR REDUCE THE FREQUENCY OF BLEEDING EPISODES IN ADULT AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER WITH HEMOPHILIA A OR B WITH OR WITHOUT FACTOR VIII OR IX INHIBITORS
NDA 219208	VANRAFIA	ATRASENTAN	NOVARTIS PHARMACEUTICALS CORP	S	4/2/2025	REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK OF RAPID DISEASE PROGRESSION, GENERALLY A URINE PROTEIN-TO-CREATININE RATIO (UPCR) = 1.5 G/G
NDA 219616	AVMAPKI FAKZYNJA CO-PACK	AVUTOMETINIB CAPSULES, 0.8 MG; DEFACTINIB TABLETS, 200 MG	VERASTEM INC	P,O	5/8/2025	THE TREATMENT OF ADULT PATIENTS WITH KRAS-MUTATED RECURRENT LOW-GRADE SEROUS OVARIAN CANCER (LGSOC) WHO HAVE RECEIVED PRIOR SYSTEMIC THERAPY

NDA 217370	TRYPTYR	ACOLTREMON	ALCON LABORATORIES INC	S	5/28/2025	FOR TREATMENT OF THE SIGNS AND SYMPTOMS OF DRY EYE DISEASE
NDA 219713	IBTROZI	TALETRECTINIB	NUVATION BIO INC	P,O	6/11/2025	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC ROS1-POSITIVE NON-SMALL CELL LUNG CANCER (NSCLC).
NDA 219839	ZEGFROVY	SUNVOZERTINIB	DIZAL (JIANGSU) PHARMACEUTICAL CO LTD	P	7/2/2025	FOR 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 219301	EKTERLY	SEBETRALSTAT	KALVISTA PHARMACEUTICALS LTD	S,O	7/3/2025	FOR THE TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN ADULTS AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER
NDA 219155	ANZUPGO	DELGOCITINIB	LEO PHARMA AS	S	7/23/2025	FOR THE TOPICAL TREATMENT OF MODERATE TO SEVERE CHRONIC HAND ECZEMA (CHE) IN ADULTS WHO HAVE HAD AN INADEQUATE RESPONSE TO, OR FOR WHOM TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE.
NDA 219666	SEPHIENCE	PTC923 (L-SEPIAPTERIN)	PTC THERAPEUTICS INC	S,O	7/28/2025	FOR THE TREATMENT OF HYPERPHENYLALANINEMIA (HPA) IN ADULT AND PEDIATRIC PATIENTS ONE MONTH OF AGE AND OLDER WITH SEPIAPTERIN-RESPONSIVE PHENYLKETONURIA (PKU). SEPHIENCE IS TO BE USED IN CONJUNCTION WITH A PHENYLALANINE (PHE)-RESTRICTED DIET.
NDA 218585	VIZZ	SEPIAPTERIN	LENZ THERAPEUTICS INC	S	7/31/2025	FOR THE TREATMENT OF PRESBYOPIA
NDA 219876	MODEYSO	DORDAVIPRONE	CHIMERIX INC	P,O	8/6/2025	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER WITH DIFFUSE MIDLINE GLIOMA HARBORING AN H3 K27M MUTATION WITH PROGRESSIVE DISEASE FOLLOWING PRIOR THERAPY.
NDA 219042	HERNEXEOS	ZONGERTINIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	8/8/2025	FOR 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-APPROVED TEST, AND WHO HAVE RECEIVED PRIOR SYSTEMIC THERAPY.
NDA 217673	BRINSUPRI	BRENSOCATIB	INSMED INC	P	8/12/2025	FOR THE TREATMENT OF NON-CYSTIC FIBROSIS BRONCHIECTASIS (NCFB) IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER
NDA 219407	DAWNZERA	DONIDALORSEN	IONIS PHARMACEUTICALS INC	S,O	8/21/2025	PROPHYLAXIS TO PREVENT ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER.

NDA 219685	WAYRILZ	RILZABRUTINIB	GENZYME CORP	S,O	8/29/2025	FOR THE TREATMENT OF ADULT PATIENTS WITH PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP) WHO HAVE HAD AN INSUFFICIENT RESPONSE TO A PREVIOUS TREATMENT.
NDA 215244	FORZINITY	ELAMIPRETIDE	STEALTH BIOTHERAPEUTICS INC	P,O	9/19/2025	FORZINITY IS INDICATED TO IMPROVE MUSCLE STRENGTH IN ADULT AND PEDIATRIC PATIENTS WITH BARTH SYNDROME WEIGHING AT LEAST 30 KG.
NDA 218881	INLURIYO	IMLUNESTRANT	ELI LILLY AND CO	S	9/25/2025	FOR THE TREATMENT OF ADULTS WITH ESTROGEN RECEPTOR (ER)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE, ESTROGEN RECEPTOR-1 (ESR1)-MUTATED ADVANCED OR METASTATIC BREAST CANCER WITH DISEASE PROGRESSION FOLLOWING AT LEAST ONE LINE OF ENDOCRINE THERAPY
NDA 219070	PALSONIFY	PALTUSOTINE	CRINETICS PHARMACEUTICALS INC	S,O	9/25/2025	FOR THE TREATMENT OF ADULTS WITH ACROMEGALY WHO HAD AN INADEQUATE RESPONSE TO SURGERY AND/OR FOR WHOM SURGERY IS NOT AN OPTION.
NDA 218436	RHAPSIDO	REMIBRUTINIB	NOVARTIS PHARMACEUTICALS CORP	P	9/30/2025	FOR THE TREATMENT OF CHRONIC SPONTANEOUS URTICARIA (CSU) IN ADULT PATIENTS WHO REMAIN SYMPTOMATIC DESPITE H1 ANTIHISTAMINE TREATMENT
NDA 218764	JASCAYD	NERANDOMILAST	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P,O	10/7/2025	FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS IN ADULT PATIENTS
NDA 219469	LYNKUET	ELINZANETANT	BAYER HEALTHCARE PHARMACEUTICALS INC	S	10/24/2025	FOR THE TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS DUE TO MENOPAUSE
NDA 219792	KYGEVVI	DOXECITINE AND DOXRIBTIMIN	UCB INC	P,O	11/3/2025	FOR 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	KOMZIFTI	ZIFTOMENIB	KURA ONCOLOGY INC	P,O	11/13/2025	FOR THE 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.
NDA 219947	REDEMPLO	PLOZASIRAN	ARROWHEAD PHARMACEUTICALS INC	S,O	11/18/2025	AS AN ADJUNCT TO DIET TO REDUCE TRIGLYCERIDES IN ADULTS WITH FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS)
NDA 219972	HYRNUO	SEVABERTINIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	11/19/2025	FOR THE 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.

NDA 218571	CARDAMYST	ETRIPAMIL	MILESTONE PHARMACEUTICALS USA INC	S	12/12/2025	FOR THE CONVERSION OF ACUTE SYMPTOMATIC EPISODES OF PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA (PSVT) TO SINUS RHYTHM IN ADULTS
NDA 219491	NUZOLVENCE	ZOLIFLODACIN	ENTASIS THERAPEUTICS INC	P	12/12/2025	FOR TREATMENT OF UNCOMPLICATED UROGENITAL GONORRHEA DUE TO NEISSERIA GONORRHOEAE IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER, WEIGHING AT LEAST 35 KG
NDA 219083	MYQORZO	AFICAMTEN	CYTOKINETICS INC	S,O	12/19/2025	FOR THE TREATMENT OF ADULTS WITH SYMPTOMATIC OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (OHCM) TO IMPROVE FUNCTIONAL CAPACITY AND SYMPTOMS.
NDA 220152	NEREUS	TRADIPITANT	VANDA PHARMACEUTICALS INC	S	12/30/2025	FOR PREVENTION OF VOMITING INDUCED BY MOTION IN ADULTS.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761394	DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK	DAIICHI SANKYO, INC.	S	1/17/2025	FOR TREATMENT OF ADULTS PATIENTS WITH UNRESECTABLE OR METASTATIC, HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE (IHC 0, IHC 1+ OR IHC 2+/ISH-) BREAST CANCER WHO HAVE RECEIVED PRIOR ENDOCRINE-BASED THERAPY AND CHEMOTHERAPY FOR UNRESECTABLE OR METASTATIC DISEASE
BLA 761258	PENPULIMAB-KCQX		AKESO BIOPHARMA CO., LTD.	S,O	4/23/2025	PENPULIMAB-KCQX IS INDICATED: • IN COMBINATION WITH EITHER CISPLATIN OR CARBOPLATIN AND GEMCITABINE, FOR THE FIRST-LINE 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.
BLA 761430	IMAAVY	NIPOCALIMAB-AAHU	JANSSEN BIOTECH, INC.	P,O	4/29/2025	FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS (GMG) IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WHO ARE ANTI-ACETYLCHOLINE RECEPTOR (ACHR) OR ANTI-MUSCLE-SPECIFIC TYROSINE KINASE (MUSK) ANTIBODY POSITIVE
BLA 761384	EMRELIS	TELISOTUZUMAB VEDOTIN-TLLV	ABBVIE INC.	P	5/14/2025	FOR 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.
BLA 761432	ENFLONSIA	CLESROVIMAB-CFOR	MERCK SHARP & DOHME LLC	P	6/9/2025	FOR THE PREVENTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV) LOWER RESPIRATORY TRACT DISEASE IN NEONATES AND INFANTS WHO ARE BORN DURING OR ENTERING THEIR FIRST RSV SEASON.
BLA 761367	ANDEMBRY	GARADACIMAB-GXII	CSL BEHRING LLC	S,O	6/16/2025	PROPHYLAXIS TO PREVENT ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN ADULT AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER

BLA 761400	LYNOZYFIC	LINVOSELTAMAB-GCPT	REGENERON PHARMACEUTICALS, INC.	P,O	7/2/2025	FOR THE 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 761467	KEYTRUDA QLEX	PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH	MERCK SHARP & DOHME LLC	P	9/19/2025	FOR THE TREATMENT OF MELANOMA, NON-SMALL CELL LUNG CANER, MALIGNANT PLEURAL MESOTHELIOMA, HEAD AND NECK SQUAMOUS CELL CANCER, UROTHELIAL CANCER, MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT CANCER, MICROSATELLITE INSTABILITY-HIGH OR MISMATCH REPAIR DEFICIENT COLORECTAL CANCER, GASTRIC CANCER, ESOPHAGEAL CANCER, CERVICAL CANCER, HEPATOCELLULAR CARCINOMA, BILIARY TRACT CANCER, MERKEL CELL CARCINOMA, RENAL CELL CARCINOMA, ENDOMETRIAL CARCINOMA, CUTANEOUS SQUAMOUS CELL CARCINOMA, TRIPLE-NEGATIVE BREAST CANCER
BLA 761434	VOYXACT	SIBEPRENLIMAB-SZSI	OTSUKA PHARMACEUTICAL COMPANY, LTD.	P	11/25/2025	REDUCE PROTEINURIA IN ADULTS WITH PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) AT RISK FOR DISEASE PROGRESSION
BLA 761427	LEROCHOL	LERODALCIBEP-LIGA) INJECTION	LIB THERAPEUTICS, INC.	S	12/12/2025	AS AN ADJUNCT TO DIET AND EXERCISE TO REDUCE LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN ADULTS WITH HYPERCHOLESTEROLEMIA, INCLUDING HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH).
BLA 761458	EXDENSUR	DEPEMOKIMAB-ULAA	GLAXOSMITHKLINE LLC	S	12/16/2025	AS AN ADD-ON MAINTENANCE TREATMENT OF SEVERE ASTHMA CHARACTERIZED BY AN EOSINOPHILIC PHENOTYPE IN ADULT AND PEDIATRIC PATIENTS AGED 12 YEARS AND OLDER
BLA 761152	YARTEMLA	NARSOPLIMAB-WUUG	OMEROS CORPORATION	P,O	12/23/2025	FOR TREATMENT OF ADULT AND PEDIATRIC PATIENTS TWO YEARS OF AGE AND OLDER WITH HEMATOPOIETIC STEM CELL TRANSPLANT-ASSOCIATED THROMBOTIC MICROANGIOPATHY (TA-TMA)

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).