Judi Health | Capital Rx

Medication Pipeline Report 2025 I Q4

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GLOSSARY:

IA ..... Intra-arterial

CVC ..... Catheter Lock Solution

ICI ..... Intracameral implant

ID ..... Intradermal

IM ..... Intramuscular

IN ..... Intranasal

INH ..... Inhaled

INJ ..... Injectable

IT ..... Intrathecal

IV ..... Intravenous

IVT ..... Intravitreal

OPHT ..... Ophthalmic

OT ..... Otic

PO ..... Oral

SC ..... Subcutaneous

TD ..... Transdermal

TOP ..... Topical

INTRODUCTION

Welcome to the Capital Rx Pipeline Report. This quarterly publication is developed by our Clinical Pharmacists and is prepared using a wide range of clinical resources. The Capital Rx Pipeline Report is designed to keep you up to date on the latest drug approvals and well-versed on what is to come in the FDA drug pipeline. Our pipeline report is one of the many ways we, at Capital Rx, demonstrate our commitment to providing clients and partners the tools and resources they desire.

WHO WE ARE

Capital Rx is a next generation pharmacy benefits manager, overseeing prescription benefit plans on behalf of employers, unions, and government entities. Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change. Through our platform approach, Capital Rx delivers data-driven insights and actionable strategies that reduce costs, while improving patient outcomes. Our commitment to innovation, technology and service is the reason why Capital Rx is among the fastest-growing PBMs in the country.

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The drug pipeline is subject to change.
Information in this report is current as of:
12/24/2025

AUKELSO™ (DENOSUMAB-KYQQ) SC BIOCON

Approval Date	09/16/2025
Indication	Hypercalcemia of malignancy, bone metastases, giant cell tumor of bone
Clinical Overview	Hypercalcemia of malignancy is most often caused by too much parathyroid hormone related peptide from tumors, cancer attacking the bone releasing calcium, or multiple myeloma tumors in the bone. Typical symptoms include fatigue, constipation, decreased appetite, bone/muscle pain, and in more severe cases, irregular heartbeat, vomiting, pain with urination, and stomach pain. Bone metastases tumors usually come from other cancer tissues in the body like breast, lung, prostate (most common), or myeloma. Bone pain that is dull is a frequent symptom of bone metastases. Giant cell tumor of the bone is an aggressive tumor that is usually localized and occurs in about 1.6 per 100,000 people in the US per year. It typically occurs in the distal femur and proximal tibia.
Considerations	• Interchangeable biosimilar of Xgeva® • Healthcare administered
Select Alt Therapies	Xgeva® (denosumab) SC, Bomyntra® (denosumab-bnht) SC, Osenvelt® (denosumab-bmwo) SC, Wyost® (denosumab-bbdz) SC, Xybrx® (denosumab-dssb) SC

BOSAYA™ (DENOSUMAB-KYQQ) SC BIOCON

Approval Date	09/16/2025
Indication	Increasing bone mass, glucocorticoid-induced osteoporosis, osteoporosis in men and postmenopausal women
Clinical Overview	Osteoporosis is caused by excessive reabsorption of bone which causes bones to weaken and become prone to fractures. It is the most common bone disease that effects more women than men. About 1 in every 3 women and 1 in every 5 men over the age of 50 develop osteoporosis. Risk factors for osteoporosis include age, female gender, previous fractures, menopause, family history, smoking, alcohol, poor nutrition, and vitamin D deficiency. Both prostate and breast cancer are frequent causes of bone metastases. Breast cancer causes an increase in osteoclast activity while prostate cancer causes an increase in osteoblast activity. Though prostate cancer causes new bone to form, it is spongy instead of compact and leads to a decrease in bone strength and function.
Considerations	• Interchangeable biosimilar of Prolia® • Healthcare administered
Select Alt Therapies	Prolia® (denosumab) SC, Conexxence® (denosumab-bnht) SC, Jubbonti® (denosumab-bbdz) SC, Stoboclo® (denosumab-bmwo) SC, Ospomyv™ (denosumab-dssb) SC

KEYTRUDA QLEX™ (BERAHYALURONIDASE ALFA; PEMBROLIZUMAB) SC MERCK & CO

Approval Date	09/19/2025
Indication	Non-small cell lung cancer (NSCLC), cutaneous squamous cell carcinoma (cSCC), colorectal cancer, bladder cancer and urothelial cancer
Clinical Overview	Lung cancer is the leading cause of US cancer related death. NSCLC accounts for about 87% of all lung cancer cases, making it the most common type of lung cancer. There are about 200,000 new NSCLC cases diagnosed yearly. CSCC is the second most common nonmelanoma skin cancer. CSCC is usually located in the head and neck area with surgical removal being the most common treatment option. Colorectal cancer is the 2nd most common cancer in women and 3rd most common cancer in men. The risk of this cancer increases with age and symptoms can include abdominal pain, nausea, vomiting, blood in stool, or exhaustion.
Considerations	• Healthcare administered in under 1 minute • Can be administered in multiple settings from an infusion center to a doctor's office or a local community-based clinic, providing more options where patients can receive their treatment • For patients who do not require a port or whose veins are difficult to access, subcutaneous administration may simplify treatment administration
Select Alt Therapies	Keytruda® (pembrolizumab) IV, Opdivo® (nivolumab) IV, Qvantig™ (nivolumab; hyaluronidase-nvhy) SC

FORZINITY™ (ELAMIPRETIDE) SC STEALTH BIOTHERAPEUTICS

Approval Date	09/19/2025
Indication	Improving muscle strength in adults and pediatrics with Barth Syndrome (BTHS) who weigh ≥30 kg
Clinical Overview	BTHS is a very rare X-linked, recessive genetic disorder that is caused by a mutation in the TAZ gene. The TAZ gene encodes the protein tafazzin. The tafazzin protein remodels cardiolipin, which is used to provide structure to the mitochondrial membrane. Without tafazzin, the mitochondria are dysfunctional, and cell energy is halted. Symptoms can consist of cardiomyopathy, neutropenia, muscle weakness, fatigue, delayed growth, and physical disability. Symptoms of BTHS usually occur in males as most female carriers are asymptomatic. It occurs in about 150 people in the US and 250 people worldwide.
Considerations	• First approved therapy for BTHS • FDA granted accelerated approval to fast track and priority review • Rare pediatric disease and orphan drug designation • Annual wholesale acquisition cost (WAC) is $795,750 per year
Select Alt Therapies	There was no approved treatment prior to approval of Forzinity™. Symptom improvement was used such as physical therapy for muscle weakness and beta blockers for heart function.

PALSONIFY™ (PALTUSOTINE) PO CRINETICS PHARMACEUTICALS

Approval Date	09/25/2025
Indication	Acromegaly
Clinical Overview	Acromegaly is a rare disease that is due to oversecretion of growth hormone (GH) due to a benign tumor of the pituitary gland. Symptoms can include abnormal enlargement in the bones of hands, feet, arms, legs, and head with symptoms occurring slowly overtime. About 27,500 people in the US have acromegaly with about 3,400 new cases per year. Acromegaly most often occurs in patients in their 40s and 50s but can occur at any age after puberty. The most common treatment option for acromegaly is removal of the pituitary gland (transsphenoidal surgery).
Considerations	• Orphan drug
Select Alt Therapies	Sandostatin® LAR (octreotide acetate) IM, Somatuline® (lanreotide) SC, Signifor® LAR (pasireotide) IM, Mycapssa® (ocetrotide) PO

INLURIYO™ (IMLUNESTRANT) PO ELI LILLY

Approval Date	09/25/2025
Indication	Mutated advanced or metastatic breast cancer with hormone receptor positive (HR+) and human epidermal growth factor 2-negative (HER2) with disease progression following ≥1 lines of endocrine therapy
Clinical Overview	The most common cancer diagnosis in the US among women is breast cancer with HR+/HER2- accounting for about 70% of cases. Only 6-10% of breast cancers are metastatic at the time of diagnosis. The main treatment therapy for management of metastatic HR+ and HER2- breast cancer is endocrine-based therapy. Endocrine therapy usually includes therapy that slows or halts growth of hormone-sensitive tumors by blocking the production of hormones in the body or preventing effects of hormones on the breast cancer cells. Currently all cyclin-dependent kinase 4/6 inhibitors are considered standard of care therapy for HR+ and HER- metastatic breast cancer.
Considerations	• Limited distribution drug available in 2 specialty pharmacies (Biologics and Onco360) • Second FDA approved oral selective estrogen receptor degrader (SERD)
Select Alt Therapies	Orserdu® (elacestrant) PO

XTRENBO™ (DENOSUMAB-QBDE) SC HIKMA PHARMACEUTICALS

Approval Date	09/26/2025
Indication	Hypercalcemia of malignancy, multiple myeloma bone metastases, bone metastases tumors, and giant cell tumor of bone
Clinical Overview	Hypercalcemia of malignancy is most often caused by too much parathyroid hormone related peptide from tumors, cancer attacking the bone releasing calcium, or multiple myeloma tumors in the bone. Typical symptoms include fatigue, constipation, decreased appetite, bone/muscle pain, and in more severe cases, irregular heartbeat, vomiting, pain with urination, and stomach pain. Bone metastases tumors usually come from other cancer tissues in the body like breast, lung, prostate (most common), or myeloma. Bone pain that is dull is a frequent symptom of bone metastases. Giant cell tumor of the bone is an aggressive tumor that is usually localized and occurs in about 1.6 per 100,000 people in the US per year. It typically occurs in the distal femur and proximal tibia.
Considerations	• Interchangeable biosimilar of Xgeva® • Healthcare administered
Select Alt Therapies	Xgeva® (denosumab) SC, Bomyntra® (denosumab-bnht) SC, Osenvelt® (denosumab-bmwo) SC, Wyost® (denosumab-bbdz) SC, Xybrx® (denosumab-dssb) SC

ENOBY™ (DENOSUMAB-QBDE) SC HIKMA PHARMACEUTICALS

Approval Date	09/26/2025
Indication	Glucocorticoid induced osteoporosis, increasing bone mass in breast cancer, osteoporosis in men and postmenopausal women
Clinical Overview	Osteoporosis is caused by excessive reabsorption of bone which causes bones to weaken and become prone to fractures. It is the most common bone disease that effects more women than men. About 1 in every 3 women and 1 in every 5 men over the age of 50 develop osteoporosis. Risk factors for osteoporosis include age, female gender, previous fractures, menopause, family history, smoking, alcohol, poor nutrition, and vitamin D deficiency. Both prostate and breast cancer are frequent causes of bone metastases. Breast cancer causes an increase in osteoclast activity while prostate cancer causes an increase in osteoblast activity. Though prostate cancer causes new bone to form, it is spongy instead of compact and leads to a decrease in bone strength and function.
Considerations	• Interchangeable biosimilar of Prolia® • Healthcare administered
Select Alt Therapies	Prolia® (denosumab) SC, Conexxence® (denosumab-bnht) SC, Jubbonti® (denosumab-bbdz) SC, Stoboclo® (denosumab-bmwo) SC, Ospomyv™ (denosumab-dssb) SC

RHAPSIDO® (REMIBRUTINIB) PO NOVARTIS

Approval Date	09/30/2025
Indication	Chronic spontaneous urticaria (CSU)
Clinical Overview	CSU is a skin condition that has symptoms of hives and/or angioedema that lasts for ≥6 weeks without a known cause. Symptoms can occur daily and may reoccur after full remission. The main causes of CSU are activation of skin mast cells and basophil degranulation with release of histamine and other inflammatory substances. The two main types of CSU are autoallergic (Type I) and autoimmune (Type IIb). CSU is common as it affects >1.5 million adults in the US and more than half of patients do not respond to H1 antihistamine therapy.
Considerations	• About $4,500 WAC for a month supply • No laboratory monitoring required • First oral targeted therapy for CSU
Select Alt Therapies	Dupixent® (dupilumab) SC, Xolair® (omalizumab) SC

EYDENZELT® (AFLIBERCEPT-BOAV) IVT CELLTRION

Approval Date	10/02/2025
Indication	Wet age-related macular degeneration, diabetic retinopathy (DR), diabetic macular edema, macular edema following retinal vein occlusion
Clinical Overview	Wet age-related macular degeneration is a condition of the eye that causes blurred vision or decreases central vision. Symptoms usually worsen quickly and may include difficulty adjusting to low light levels, need for brighter lights when reading, visual distortions, and difficulty recognizing faces. This disease is most common in those ≥50 years old and is 20% of all age-related macular degeneration. DR and diabetic macular edema are caused by damage overtime to the structures of the retina. DR and macular edema are major complications of diabetes with about 75% of people with type I diabetes developing DR and 25% of those with diabetes developing macular edema. Blockage to a vein that carries blood away from the retina can lead to a retinal vein occlusion. RVOs can cause swelling of the macula leading to blurry vision and even vision loss.
Considerations	• Healthcare administered • Sixth biosimilar available in the US for Eylea®
Select Alt Therapies	Pavblu™ (aflibercept-ayyh) IVT, Yesafili™ (aflibercept-jbvf) IVT, Opuviz™ (aflibercept-yszy) IVT, Eylea® (aflibercept) IVT, Enzeevu™ (aflibercept-abzv) IVT, Ahzantive® (aflibercept-mrbb) IVT

JASCAYD® (NERANDOMILAST) PO BOEHRINGER INGELHEIM

Approval Date	10/07/2025
Indication	Idiopathic pulmonary fibrosis (IPF)
Clinical Overview	IPF is a progressive disease that causes a decrease in lung function due to fibrosing interstitial pneumonia. It mainly affects older patients that are in their 50s or 60s. Symptoms can include progressive shortness of breath, dry cough, fatigue, dry inspiratory crackles, and nail clubbing. IPF is also associated with a higher rate of lung cancer, especially in those who smoke or have a smoking history. Patients with IPF have increased mortality as the average time of survival after diagnosis is 3-4 years.
Considerations	• First approval of this indication in >10 years • $16,000 WAC for a month supply
Select Alt Therapies	Ofev® (nintedanib) PO, Esbriet® (pirfenidone) PO

EPIOXA™/EPIOXA HD™ (RIBOFLAVIN 5'-PHOSPHATE) OPHT GLAUKOS

Approval Date	10/17/2025
Indication	Keratoconus (KC) in patients ≥13 years old
Clinical Overview	KC is a progressive eye disease that causes the cornea to thin and weaken over time, leading to a cone-like bulge appearing in the cornea. Symptoms can include a significant decrease in vision and irregular stromal thinning. It is a disease that occurs in both of the eyes, though symptoms can be more severe in one eye compared to the other. KC typically starts in early adulthood or late childhood years and stops progressing after 40 years old. KC occurs in about 50-230 people per 100,000.
Considerations	• First topical treatment that does not require removal of corneal epithelium • Healthcare administered
Select Alt Therapies	No medication therapy existed prior to the approval of Epioxa™/Epioxa™ HD instead; the corneal cross-linking procedure was used as treatment.

KYGEVVI™ (DOXECITINE; DOXRIBTIMINE) PO UCB ZOGENIX

Approval Date	11/03/2025
Indication	Thymidine kinase 2 deficiency (TK2d) in patients with symptom onset at ≤12 years old
Clinical Overview	TK2d is an ultra-rare disorder that is inherited and is caused by mutations in the TK2 gene. These mutations lead to the body not producing and repairing mitochondrial DNA. Exact prevalence of this disorder is unknown, but about 120 cases have been reported nationally. Symptoms can include respiratory failure, progressive muscle weakness, and problems with swallowing/chewing. TK2d is classified into three forms depending on the age symptoms develop: infantile onset (<1 year old), childhood-onset (1-12 years old), and late-onset (12 years old).
Considerations	• First treatment approved for TK2d • Orphan drug
Select Alt Therapies	Prior to the approval of Kygevvi™, no therapies existed for treatment of TK2d. Instead, supportive therapy with respiratory care and muscle weakness symptom control were utilized.

KOMZIFTI™ (ZIFTOMENIB) PO KURA ONCOLOGY, KYOWA KIRIN

Approval Date	11/13/2025
Indication	Relapsed or refractory acute myeloid leukemia (AML) with a nucleophosmin 1 (NPM1) mutation
Clinical Overview	AML is cancer of the blood where immature myeloid cells grow uncontrollably. AML accounts for 1/3 of leukemia cases with about 20,000 new cases reported in the US each year. The NPM1 mutation is about 30% of AML cases. AML occurs in adults usually ≥69 years old. Many patients obtain full remission with treatment of chemotherapy, but AML does have a high relapse rate.
Considerations	• Boxed warning for differentiation syndrome (life-threatening reaction with symptoms of fever, edema, and hypoxia) • No boxed warning for QTc prolongation and Torsades de Pointes unlike Revuforj® • Onco360 Oncology Pharmacy and McKesson are the limited specialty pharmacy providers
Select Alt Therapies	Revuforj®(revumenib) PO

POHERDY® (PERTUZUMAB-DPZB) IV ORGANON HENLIUS

Approval Date	11/13/2025
Indication	Human epidermal growth factor (HER2+) breast cancer
Clinical Overview	HER2+ breast cancer is an invasive and fast-growing breast cancer. About 290,000 women are estimated to have an invasive type of breast cancer in 2023. Out of those breast cancers, 15-20% will be HER2+ breast cancers. Symptoms can consist of a mass or lump in the breast, change in shape or color of the breast, or blood-stained/clear fluid coming from the nipple. HER2+ breast cancer is caused by a mutation in the HER2 gene. Risk factors can consist of history of breast cancer, starting menopause later than normal, having an inherited mutation like BRCA1, or taking hormone replacement therapy.
Considerations	• First interchangeable biosimilar to Perjeta® • Boxed warning for left ventricular dysfunction and embryo fetal toxicity • Healthcare administered
Select Alt Therapies	Perjeta® (pertuzumab) IV

REDEMPLO® (PLOZASIRAN) SC ARROWHEAD

Approval Date	11/18/2025
Indication	Familial chylomicronemia syndrome (FCS)
Clinical Overview	FCS is a rare genetic disorder that causes very high triglyceride levels which can lead to acute pancreatitis. FCS occurs in about 6,500 people in the US. Typical fasting levels of triglycerides are ≥880 mg/dL in patients with FCS, and they usually have a history of pancreatitis. Initial onset typically occurs in the childhood years, but it can go unrecognized until adulthood. Symptoms may include nausea, vomiting, eruptive xanthomas, forgetfulness, retinalis, hepatosplenomegaly, failure to thrive, and recurrent episodes of mild to severe abdominal pain.
Considerations	• Self-administered every 3 months • First and only FDA approved medication studied in those genetically diagnosed • 90% lower annual WAC compared to Trynglоza™ ($60,000 vs $595,008 annual WAC)
Select Alt Therapies	Trynglоza™ (olezarsan) SC

HYRNUO® (SEVABERTINIB) PO BAYER

Approval Date	11/19/2025
Indication	Locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 Erb-B2 receptor tyrosine kinase 2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy
Clinical Overview	Lung cancer is the main cause of cancer-related death in the US with ≥226,650 new cases occurring annually. NSCLC is ≥85% of lung cancer cases, and there are about 2-4% of HER2 mutations in advanced NSCLC cases. HER2 gene mutations most commonly occur in younger, female patients who have never smoked. HER2 mutations have shown an increased incidence of brain metastases.
Considerations	• FDA granted accelerated approval • Onco360 is the designated national pharmacy partner
Select Alt Therapies	Hernexos® (zongertinib) PO

OSVYRTI® (DENOSUMAB-DESU) SC ACCORD INTAS

Approval Date	11/20/2025
Indication	Increasing bone mass from breast cancer or prostate cancer treatment, glucocorticoid-induced osteoporosis, osteoporosis for postmenopausal women and men
Clinical Overview	Osteoporosis is caused by excessive reabsorption of bone which causes bones to weaken and become prone to fractures. It is the most common bone disease that effects more women than men. About 1 in every 3 women and 1 in every 5 men over the age of 50 develop osteoporosis. Risk factors for osteoporosis include age, female gender, previous fractures, menopause, family history, smoking, alcohol, poor nutrition, and vitamin D deficiency. Both prostate and breast cancer are frequent causes of bone metastases. Breast cancer causes an increase in osteoclast activity while prostate cancer causes an increase in osteoblast activity. Though prostate cancer causes new bone to form, it is spongy instead of compact and leads to a decrease in bone strength and function.
Considerations	• Interchangeable biosimilar to Prolia® • Healthcare administered
Select Alt Therapies	Prolia® (denosumab) SC, Conexxence® (denosumab-bnht) SC, Jubbonti® (denosumab-bbdz) SC, Stoboclo® (denosumab-bmwo) SC, Ospomyv™ (denosumab-dssb) SC

JUBEREQ® (DENOSUMAB-DESU) SC ACCORD INTAS

Approval Date	11/20/2025
Indication	Hypercalcemia of malignancy, multiple myeloma bone metastases, bone metastases tumors, and giant cell tumor of bone
Clinical Overview	Hypercalcemia of malignancy is most often caused by too much parathyroid hormone related peptide from tumors, cancer attacking the bone releasing calcium, or multiple myeloma tumors in the bone. Typical symptoms include fatigue, constipation, decreased appetite, bone/muscle pain, and in more severe cases, irregular heartbeat, vomiting, pain with urination, and stomach pain. Bone metastases tumors usually come from other cancer tissues in the body like breast, lung, prostate (most common), or myeloma. Bone pain that is dull is a frequent symptom of bone metastases. Giant cell tumor of the bone is an aggressive tumor that is usually localized and occurs in about 1.6 per 100,000 people in the US per year. It typically occurs in the distal femur and proximal tibia.
Considerations	• Interchangeable biosimilar to Xgeva® • Healthcare administered
Select Alt Therapies	Xgeva® (denosumab) SC, Bomyntra® (denosumab-bnht) SC, Osenvelt® (denosumab-bmwo) SC, Wyost® (denosumab-bbdz) SC, Xybrx® (denosumab-dssb) SC

ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE) IT NOVARTIS, AVEXIS

Approval Date	11/24/2025
Indication	Spinal muscular atrophy (SMA) in patients ≥2 years old with a confirmed mutation in the survival motor neuron 1 (SMN1) gene
Clinical Overview	SMA is a progressive, yet rare neuromuscular disease that can show up differently based on the subtype. It is caused by mutations or deletions in the SMN1 gene that produces the SMN protein. SMA is classified by severity into 4 types (Types 1-4). The severity of the disease is caused by the number of SMN2 copies present and the ability for them to create a functional SMN protein. Common symptoms of SMA include muscle weakness, atrophy, hypotonia, decreased or absent reflexes, and twitching of muscle fibers.
Considerations	• Gene therapy • One-time fixed dose intrathecal injection • Available through Accredo, Orsini, and Axium/Farmacia Doral specialty pharmacies • Boxed warning for risk of acute serious liver injury and elevated aminotransferases
Select Alt Therapies	Zolgensma® (onasemnogene abeparvovec-xioi) IV, Spinraza® (nusinersen) IT, Evrysdi® (risdiplam) PO

VOYXACT® (SIBEPRENLIMAB-SZSI) SC OTSUKA VISTERRA

Approval Date	11/25/2025
Indication	Immunoglobulin A (IgA) nephropathy
Clinical Overview	IgA nephropathy, also known as Berger disease, is a kidney disorder that occurs from immunoglobulin A building up in the kidneys. Symptoms can include blood in the urine, foamy urine, pain on one or both sides of the back, high blood pressure, weakness, swelling of the hands/feet, and in severe cases, kidney failure. This disease can develop usually around the teens or 30s. The cause of IgA nephropathy is not well known, but certain things that might be linked are liver diseases, infections, and genes.
Considerations	• Self-administered subcutaneous injection given once every 4 weeks • Granted FDA accelerated approval • Has no boxed warnings unlike other treatment options
Select Alt Therapies	Fabhalta® (iptacopan) PO, Filspari® (sparsentan) PO, Tarpeyo® (budesonide) PO, and Vanrafia® (atrasentan) PO

ARMLUPEG™ (PEGFILGRASTIM-UNNE) SC LUPIN, VALORUM BIOLOGICS

Approval Date	11/28/2025
Indication	Decreases incidence of infection due to febrile neutropenia and increases survival in patients receiving myelosuppressive chemotherapy
Clinical Overview	Febrile neutropenia is when a patient has a fever (≥101 F°) with an absolute neutrophilic count (ANC) of <1,500 cells/microliter. Febrile neutropenia is the most common complication of cancer therapy, and about 50% of patients will develop infection. Cancer treatment causes white blood cells (neutrophils) to decrease, making it hard for the body to fight infection. Armlupeg works to increase white blood cells by stimulating bone marrow.
Considerations	• Biosimilar of Neulasta® • Healthcare administered
Select Alt Therapies	Neulasta® (pegfilgrastim) SC, Fulphila® (pegfilgrastim-jmdb) SC, Udenyca® (pegfilgrastim-cbqv) SC, Ziexenzo® (pegfilgrastim-bmez) SC, Nyvepria® (pegfilgrastim-apgf) SC, Fylnetra® (pegfilgrastim-pbbk) SC, and Stimufend® (pegfilgrastim-fpgk) SC

WASKYRA™ (ETUVETIDIGENE AUTOTEMCEL) IV FONDAZIONE TELETHON, GSK

Approval Date	12/03/2025
Indication	Wiskott-Aldrich syndrome (WAS) in patients ≥6 months old
Clinical Overview	WAS is a rare genetic blood disorder that results from mutations in the WAS gene on the X chromosome. Mutations lead to immunodeficiency, thrombocytopenia, and eczema. Eczema typically starts to develop in the first year of life in one-half of patients. Bleeding is present at birth, and malignancies occur most often in adolescents to young adults. WAS occurs in 1 in every 10,000 births and is seen almost solely in the male population.
Considerations	• First and only approved gene therapy for WAS • FDA orphan drug status • Rare pediatric disease and regenerative medicine advanced therapy designation by FDA
Select Alt Therapies	The only treatment option prior to the approval of Waskyra™, was preforming a hematopoietic stem cell transplant (HSCT).

LEROCHOL™ (LERODALCIBEP-LIGA) SC LIB THERAPEUTICS

Approval Date	12/12/2025
Indication	Hypercholesterolemia and heterozygous familial hypercholesteremia (HeFH)
Clinical Overview	Hypercholesterolemia (high cholesterol) is defined as having bad cholesterol (LDL) ≥190 mg/dL. Some risk factors can include high blood pressure, diabetes, smoking, and history of premature atherosclerotic cardiovascular disease. About 31.7% of adults have high cholesterol in the US and are at twice the risk of developing heart disease. Familial hypercholesteremia is a genetic inherited disorder that makes the body deficient in recycling bad cholesterol. The two types of familial hypercholesteremia are heterozygous and homozygous, with heterozygous being the most common of the two. Patients with HeFH inherit one familial hypercholesteremia gene from one parent. About 1.3 million people are affected by familial hypercholesteremia in the US. Patients with HeFH can start to develop heart disease in their 30s.
Considerations	• Stable at room temperature for 3 months • Self-administered
Select Alt Therapies	Praluent® (alirocumab) SC, Repatha® (evolocumab) SC

EXDENSUR™ (DEPEMOKIMAB-ULAA) SC GSK

Approval Date	12/16/2025
Indication	Eosinophilic asthma for patients ≥12 years old
Clinical Overview	Eosinophilic asthma is a subtype of asthma where the number of eosinophils is increased in the blood and lung tissue. This subtype of asthma tends to be more severe and usually develops in adulthood between 35-50 years old. About 10% of all asthma cases are severe. Symptoms can include wheezing, coughing, chest tightness, shortness of breath, and chronic rhinosinusitis with nasal polyps.
Considerations	• Healthcare administered • First ultra long-acting treatment (dosed every 6 months)
Select Alt Therapies	Fasenra® (benralizumab) SC, Dupixent® (dupilumab) SC, Nucala® (mepolizumab) SC, Cinqair® (reslizumab) IV

MYQORZO™(AFICAMTEN) PO CYTOKINETICS

Approval Date	12/19/2025
Indication	Symptomatic hypertrophic cardiomyopathy (HCM)
Clinical Overview	HCM is a type of genetic heart disease where the heart muscle is thickened, making it harder for the heart to pump blood. Symptoms can include chest pain, fainting, sensation of fast or pounding heartbeats, and shortness of breath. The main risk factor is genetics, as people with one parent with HCM have a 50% chance of acquiring the gene. Complications of HCM may include atrial fibrillation, blocked blood flow, mitral valve disease, heart failure, and dilated cardiomyopathy.
Considerations	• Boxed warning for risk of heart failure due to reduced left ventricular ejection fraction • Risk Evaluation and Mitigation Strategies (REMS) program required
Select Alt Therapies	Camzyos® (mavacamten) PO

LYNKUET® (ELINZANETANT) PO BAYER

Approval Date	10/24/2025
Indication	Vasomotor symptoms (hot flashes) due to menopause
Clinical Overview	Hot flashes or night sweats occur in about 75-80% of women in menopause making them the most common symptoms of menopause. Vasomotor symptoms like hot flashes typically start with sudden feelings of heat centered on the upper chest and face and then spread through the rest of the body lasting 2-4 minutes. Symptoms can include profuse sweating, chills, shivers, and anxiety. Disruption of sleep can occur at night due to symptoms, and symptoms can occur as frequently as once per hour. Vasomotor symptoms are classified as mild, moderate, and severe with an average total duration of 7.4 years. Menopausal hormone therapy (MHT) is the gold standard treatment for vasomotor symptoms.
Considerations	• Annual WAC is $7,604 • Has no boxed warning for hepatotoxicity (unlike Veozah®)
Select Alt Therapies	Veozah® (fezolinetant) PO

NUZOLVENCE® (ZOLIFLODACIN) PO ENTASIS THERAPEUTICS

Approval Date	12/12/2025
Indication	Gonorrhea in patients ≥12 years old
Clinical Overview	Gonorrhea is a sexually transmitted infection that can cause the genitals, throat, and rectum to become infected. Gonorrhea commonly occurs in ages 15-24 years old but can occur at any age. Patients can have no symptoms at all, but it can later cause major health problems. Symptoms may include painful urination, swollen testicles (in men), increased vaginal discharge (in women), and vaginal bleeding between periods (in women). It is spread through oral, vaginal, or anal sex without a condom.
Considerations	• First in class, single dose antibiotic
Select Alt Therapies	Blujepa® (gepotidacin) PO, or a combination of an antibiotic shot and oral antibiotic (example: Ceftriaxone IM + Azithromycin PO)

ADDITIONAL BRAND APPROVALS

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Koselugo® selumetinib	Pfizer, AstraZeneca	PO	Pediatrics ≥1 year old with neurofibromatosis type 1 (NF1)	09/10/2025
Enbumyst™ bumetanide	Corstasis Therapeutics	IN	Edema related to congestive heart failure, liver disease, and kidney disease	09/12/2025
Vyjuvek® beremagene geperpavec-svdt	Krystal Biotech	TOP	Epidermolysis bullosa for patients of all ages	09/12/2025
Subvenite® lamotrigine	OWP Pharmaeuticals	New formulation: Oral solution	Epilepsy, bipolar disorder	09/16/2025
Opzelura® ruxolitinib phosphate	Incyte	TOP	Atopic dermatitis	09/18/2025
Tremfya® guselkumab	Johnson & Johnson	New formulation: SC	Plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease	09/19/2025
Bondlido® lidocaine	MedRx DWTI	New formulation: 10% strength TOP	Pain with postherpetic neuralgia	09/24/2025
Evkeeza® evinacumab	Regeneron	IV	Pediatrics ≥1 year old with homozygous familial hypercholesteremia	09/25/2025
Qivigy® immune globulin human 10% solution	Kedrion	IV	Primary immunodeficiency in adults	09/26/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Clotic® clotrimazole	Laboratorios Salvar Carwin	OTIC	Fungal otitis externa	09/26/2025
Tecentriq Hybreza™ atezolizumab; hyaluronidase	Roche Genetech	SC	Small cell lung cancer in combination with Zepzelca®	10/02/2025
Tecentriq® atezolizumab	Roche Genetech	IV	Small cell lung cancer in combination with Zepzelca®	10/02/2025
Zepzelca® lurbinectedin	PharmaMar, Jazz Pharmaceuticals	IV	Extensive small cell lung cancer in combination with Tencentriq® or Tecentriq Hybreza™	10/02/2025
Zoryve® roflumilast	Arcutis	TOP	Atopic dermatitis in children ages 2-5 years old	10/04/2025
Lasix® ONYU furosemide	Ligand Pharmaceuticals	New formulation: SC (drug-device combination)	Chronic heart failure	10/07/2025
Simponi® golimumab	Johnson & Johnson	SC	Pediatrics with ulcerative colitis who are ≥2 years old and weigh ≥15 kg	10/07/2025
Libtayo IV® cemiplimab	Sanofi, Regeneron	IV	Cutaneous squamous cell carcinoma (CSCC)	10/08/2025
Uzedy® risperidone	Teva MedinCell	SC	Maintenance treatment of bipolar I disorder	10/10/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Ferabright™ feruomoxytol	Covis Pharma	IV	Diagnostic agent for MRIs	10/16/2025
Simlandi® adalimumab-ryvk	Teva Alvotech	SC	Hidradenitis suppurativa (HS) in those ≥12 years old and pediatric uveitis (≥2 years old)	10/16/2025
Yuflyma® adalimumab-aaty	Celltrion	SC	Hidradenitis suppurativa (HS) in those ≥12 years old and pediatric uveitis (≥2 years old)	10/16/2025
Hyrimoz HCF® and Hyrimoz® adalimumab-adaz	Sandoz	SC	Hidradenitis suppurativa (HS) in those ≥12 years old and pediatric uveitis (≥2 years old)	10/16/2025
Cyltezo® and Cyltezo HC® adalimumab-adbm	Boehringer Ingelheim	SC	Hidradenitis suppurativa (HS) in those ≥12 years old and pediatric uveitis (≥2 years old)	10/16/2025
Amjevita HCF™ adalimumab-atto	Amgen	SC	Hidradenitis suppurativa (HS) and uveitis	10/16/2025
Amjevita™ adalimumab-atto	Amgen	SC	Hidradenitis suppurativa (HS) and uveitis	10/16/2025
Xeljanz® tofacitnib Citrate	Pfizer	PO (new oral solution and tablet)	Pediatrics with psoriatic arthritis in patients ≥2 years old	10/16/2025
Tezspire® tezepelumab	AstraZeneca, Amgen	SC	Chronic rhinosinusitis with nasal polyps (CRSwNP) in patients ≥12 years old	10/17/2025
Rybelsus® semaglutide	Novo Nordisk	PO	Reduce risk of major adverse cardiovascular events (MACE) in patients with type 2 diabetes	10/17/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Gazyva® obinutuzumab	Roche Genetech	IV	Lupus nephritis	10/17/2025
Contepo™ fosfomycin	Zavante Meitheal	IV	Complicated urinary tract infections and pyelonephritis in adults	10/22/2025
Blenrep® belantamab mafodotin-blmf	GSK	IV	Multiple myeloma	10/23/2025
Dehydrated Alcohol dehydrated alcohol	Royal Pharmaceuticals	INJ	Methanol poisoning	10/23/2025
Javadin™ clonidine hydrochloride	Azuirty Pharmaceuticals	New formulation: PO solution	Hypertension	10/23/2025
Revuforj® revumenib	Syndax	PO	Pediatric (≥1 year old) and adults with relapsed or refractory acute myeloid leukemia	10/24/2025
Rocuronium Bromide rocuronium bromide	Sterinova (new manufacturer)	IV	General anesthesia, skeletal muscle relaxation, and to facilitate tracheal intubation	10/24/2025
Winrevair™ sotatercept	Bristol-Myers Squibb Merck & Co	SC	Pulmonary arterial hypertension	10/24/2025
Opdivo Qvantig™ hyaluronidase-NVHY; nivolumab	Bristol-Myers Squibb Merck & Co	SC	Colorectal cancer	10/27/2025
Aukelso™ denosumab-kyqq	Biocon	SC	Interchangeable designation with Xgeva®	10/29/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Bosaya™ densoumab-kyqq	Biocon	SC	Interchangeable designation with Prolia®	10/29/2025
Conexxence® denosumab-bnht	Fresenius Kabi	SC	Interchangeable designation with Prolia®	10/29/2025
Bomyntra® denosumab-bnht	Fresenius Kabi	SC	Interchangeable designation with Xgeva®	10/29/2025
Stoboclo® denosumab-bmwo	Celltrion	SC	Interchangeable designation with Prolia®	10/29/2025
Osenvelt® denosumab-bmwo	Celltrion	SC	Interchangeable designation with Xgeva®	10/29/2025
Bilprevda® denosumab-nxxp	Organon Henlius	SC	Interchangeable designation with Xgeva®	10/29/2025
Bildyos® denosumab-nxxp	Organon Henlius	SC	Interchangeable designation with Prolia®	10/29/2025
Enoby™ denosumab-qbde	Hikma Gedeon Richter	SC	Interchangeable designation with Prolia®	10/29/2025
Xtrenbo™ denosumab-qbde	Hikma Gedeon Richter	SC	Interchangeable designation with Xgeva®	10/29/2025
Xbryk® denosumab-dssb	Samsung Bioepis	SC	Interchangeable designation with Xgeva®	10/29/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Ospomyv™ denosumab-dssb	Samsung Bioepis	SC	Interchangeable designation with Prolia®	10/29/2025
Linzess™ linaclotide	Allergan Ironwood	PO	Irritable bowel syndrome with constipation in pediatric patients ≥7 years old	11/04/2025
Caplyta® lumateperone tosylate	Intra-Cellular Therapies	PO	Major depressive disorder	11/05/2025
Darzalex Faspro® daratumumab; hyaluronidase	Johnson & Jonhson	SC	High-risk smoldering multiple myeloma	11/06/2025
Epkinly® epcoritamab	AbbVie Genmab	SC	Follicular lymphoma	11/18/2025
Imdelltra® tarlatamab-dlle	Amgen	IV	Extensive stage small cell lung cancer	11/19/2025
Koselugo® selumetinib sulfate	Pfizer, AstraZeneca	PO	Neurofibromatosis type 1 in adults who have inoperable plexiform neurofibromas	11/19/2025
Eylea HD® aflibercept	Regeneron	IVT	Macular edema following retinal vein occlusion (RVO)	11/19/2025
Keytruda Qlex™ berahyaluronidase alfa; rembrolizumab	Merch & Co, Alteogen	SC	Perioperative treatment for adults with muscle-invasive bladder cancer (MIBC)	11/21/2025
Padcev® enfortumab vedotin	Pfizer	IV	Perioperative treatment for adults with muscle-invasive bladder cancer (MIBC) used in combination with Keytruda®	11/21/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Keytruda IV™ pembrolizumab	Merch & Co	IV	Perioperative treatment for adults with muscle-invasive bladder cancer (MIBC) used in combination with Padcev®	11/21/2025
Nexlizet™ bempedoic acid; ezetimibe	Esperion Therapeutics	PO	Reduce cardiovascular events in patients with or at high risk of developing atherosclerotic cardiovascular disease	11/21/2025
Nexletol® bempedoic acid	Esperion Therapeutics	PO	Reduce cardiovascular events in patients with or at high risk of developing atherosclerotic cardiovascular disease	11/25/2025
Imfinzi® durvalumab	AstraZeneca	IV	Resectable gastric or gastroesophageal junction cancer	11/25/2025
Jayprica® pirtobrutinib	Eli Lilly; Loxo Oncology	PO	Chronic lymphocytic leukemia and small lymphocytic lymphoma	12/02/2025
Avance® acellular nerve allograft	AxoGen	Implant	Peripheral nerve discontinuation	12/03/2025
Breyanzi® lisocabtagene maraleucel	Bristol-Myers Squibb; Celgene	IV	Relapsed or refractory marginal zone lymphoma (MZL)	12/04/2025
Omisirge® omidubicel	Gamida Cell	IV	Severe aplastic anemia	12/05/2025
Uplizna® inebilizumab	AstraZeneca, Amgen	IV	Myasthenia gravis	12/11/2025
Blujepa® gepotidacin mesylate	GSK	PO	Gonorrhea	12/11/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Daybue® Stix trofinetide	Acadia Pharmaceuticals	New powder formulation: PO	Rett Syndrome	12/11/2025
Akeega® abiraterone acetate; niraparib tosylate	Johnson & Johnson	PO	BRCA2-mutated metastatic castration-sensitive prostate cancer	12/12/2025
Addyi® fibanserin	Sprout Pharmaceuticals	PO	Female sexual dysfunction for both premenopausal women and postmenopausal women <65 years old	12/13/2025
Enhertu® fam-trastuzumab deruxtecan	AstraZeneca, Daiichi Sankyo	IV	HER2+ unresectable or metastatic breast cancer	12/15/2025
Vybrique™ sildenafil citrate	IBSA	New formulation: PO film	Erectile dysfunction	12/16/2025
Fesilty™ fibrinogen, human	Grifols; Biotest Pharmaceuticals	IV	Acute bleeding episodes in patients with fibrinogen deficiency	12/16/2025
Rubraca® rubcaparib camsylate	Clovis Oncology	PO	BRCA-mutated metastatic castration-resistant prostate cancer	12/17/2025
Rybrevant Faspro™ amivantamab; hyaluronidase	Johnson & Johnson	New formulation: SC	Non-small cell lung cancer (NSCLC)	12/17/2025
Vraylar® cariprazine hydrochloride	Allergan; AbbVie	PO	Pediatrics (10-17 years old) who need acute treatment of manic or mixed episodes of bipolar I disorder and pediatrics (13-17 years old) with schizophrenia	12/18/2025
Jascayd® nerandomilast	Boehringer Ingelheim	PO	Progressive pulmonary fibrosis	12/19/2025

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BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Lunsumio Velo™ monsunetuzumab-axgb	Roche Genentech	New formulation: SC	Follicular lymphoma	12/19/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
narsoplimab	Omeros	IV	Thrombotic microangiopathy (TMA)	12/26/2025
tradipitant	Vanda Pharmaceuticals	PO	Motion sickness	12/30/2025
relacorilant	Corcept Therapeutics	PO	Cushing's syndrome	12/30/2025
semaglutide	Novo Nordisk	SC	Heart failure in patients with obesity	2H 2025
talazoparib tosylate	Pfizer	PO	Prostate cancer	2H 2025
denosumab-tvb	Teva	SC	Glucocorticoid-induced osteoporosis, osteoporosis in postmenopausal women and men, and increasing bone mass in breast cancer or prostate cancer	2H 2025
afilbercept	Alvotech Teva	IVT	Wet age-related macular degeneration	4Q 2025
denosumab-mbo9	Frensenius Kabi; mAbxience	SC	Glucocorticoid-induced osteoporosis, osteoporosis in postmenopausal women and men, and increasing bone mass in breast cancer or prostate cancer	4Q 2025
denosumab-mbo9	Frensenius Kabi; mAbxience	SC	Hypercalcemia of malignancy, giant cell tumor of bone, bone metastases	4Q 2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
teplizumab	Sanofi, Provention Bio	IV	Delay of type 1 diabetes	4Q 2025
semaglutide	Novo Nordisk	PO	Obesity and reduce cardiovascular mortality in patients with obesity	4Q 2025
bitopertin	Disc Medicine	PO	X-linked protoporphyria (XLP) and erythropoietic protoporphyria (EPP)	4Q 2025
denosumab-avto3	Dr. Reddy's Laboratories; Alvogen; Alvotech	SC	Glucocorticoid-induced osteoporosis, osteoporosis in postmenopausal women and men, and increasing bone mass in breast cancer or prostate cancer	12/2025
denosumab-avto3	Dr. Reddy's Laboratories; Alvotech	SC	Hypercalcemia of malignancy, giant cell tumor of bone, bone metastases	12/2025
bevacizumab	Outlook Therapeutics	OPHT	Wet age-related macular degeneration	12/31/2025
tasimelteon	Vanda Pharmaceuticals	PO	Jet lag disorder	01/07/2026
tabelecleucel	Pierre Fabre; Atara Biotherapeutics	IV	Post-transplant lymphoproliferative disorder (PTLD)	01/10/2026
imiglucerase	Genzyme	IV	Type 3 Gaucher disease	01/13/2026
sparsentan	Ligand Pharmaceuticals; Retrophin; Travere Therapeutics	PO	Focal segmental glomerulosclerosis	01/13/2026

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copper histidinate	Zydus; Sentynel Therapeutics; Fortress Biotech; Cyprium	SC	Menkes disease	01/14/2026
brimonidine tartrate; carbachol	Visus Therapeutics; Tenpoint Therapeutics	OPHT	Presbyopia	01/28/2026
dibutepinephrine	Aquestive Therapeutics	PO	Anaphylactic reactions	01/31/2026
leniolisib phosphate	Novartis Pharming	PO	Activated pl3Kdelta syndrome/p110delta-activating mutation causing senescent T-cells, lymphadenopathy and immunodeficiency	01/31/2026
clemidsogene lanparvovec	Nippon Shinyaku; Regenxbio	INJ	Mucopolysaccharidosis II (Hunter syndrome)	02/08/2026
pembrolizumab	Merch & Co	IV	Ovarian cancer	02/20/2026
milsaperidone	Vanda Pharmaceuticals	PO	Schizophrenia and acute treatment of bipolar disorder I	02/21/2026
desmopressin	Eton Pharmaceuticals	PO	Management of central cranial diabetes insipidus	02/25/2026
ceszuridine; decitabine	Otsuka; Astex Pharmaceuticals; Taiho	PO	Acute myeloid leukemia	02/25/2026
axicabtagene ciloleucel	Gilead; Kite Pharma	IV	Primary central nervous system lymphoma (PCNSL)	02/2026

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navepegritide	Ascendis	SC	Achondroplasia	02/28/2026
pegvaliase	BioMarin	SC	Phenylketonuria	02/28/2026
cupliumab	Sanofi; Genzyme; Regeneron	SC	Chronic rhinosinusitis	02/28/2026
idebenone	Santhera	PO	Leber's hereditary optic neuropathy (LHON)	02/28/2026
deucravacitinib	Bristol-Myers Squibb	PO	Psoriatic arthritis	03/06/2026
piflufolastat F 18	Progenics; Lantheus Medical Imaging	IV	For diagnostic imagining of kidney cancers	03/06/2026
reproxalap	AbbVie; Aldeyra	OPHT	Dry eye	03/16/2026
setmelanotide acetate	Rhythm Pharmaceuticaks	SC	Hypothalamic obesity	03/20/2026
linerixibat	GSK	PO	Pruritus in primary biliary cholangitis	03/24/2026
marnetegragene autotemcel	Rocket Pharma	IV	Leukocyte adhesion deficiency (LAD)	03/28/2026

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gallium-68 edotreotide	Lantheus Medical Imaging; Jubiliant; Evergreen	IV	PET localization of neuroendocrine tumors	03/29/2026
ferric maltol	Shield Therapeutics	PO	Iron deficiency	1Q 2026
semaglutide (7.2 mg dose)	Novo Nordisk	SC	Obesity	1Q 2026
doxorubicin	SkinJect Medicus	TD	Basal cell carcinoma	1Q 2026
somapacitan	Novo Nordisk	SC	Idiopathic short stature; short stature associated with Noonan syndrome	1Q 2026
fam-trastuzumab deruxtecan	AstraZeneca; Daiichi Sankyo	IV	Gastric cancer; Gastroesophageal junction cancer	1Q 2026
insulin icodec	Novo Nordisk	SC	Type 2 diabetes glucose control	03/2026
nusinersen	Biogen Ionis Pharmaceuticals	IT	Spinal muscular atrophy	04/03/2026
tividenofusp Alfa	Denali Therpaeutics	IV	Mucopolysaccharidosis II (Hunter syndrome)	04/05/2026
orca-T (TBD)	Orca Bio	INJ	Conditioning for allogeneic hematopoietic stem cell transplantation	04/06/2026

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nivolumab	Bristol-Myers Squibb; Onto Pharmaceutical	IV	Hodgkin's lymphoma	04/08/2026
vusolimogene oderparepvec	Replimune	INJ	Melanoma	04/10/2026
nimodipine	Acasti Grace Therapeutics	IV	Subarachnoid hemorrhage	04/23/2026
isatuximab	Sanofi; AbbVie; ImmunoGen	SC	Multiple myeloma	04/23/2026
dupilumab	Sanofi; Genzyme; Regeneron	SC	Chronic idiopathic urticaria (CIU)	04/27/2026
doravirine; islatravir	Merck & Co	PO	HIV-1 infection	04/28/2026
ustekinumab	Johnson & Johnson	SC	Crohn's disease	04/2026
ustekinumab	Johnson & Johnson	IV	Crohn's disease	04/2026
golimumab	Accord; Intas Bio-Thera Solutions	SC	Ulcerative colitis; ankylosing spondylitis; rheumatoid arthritis; psoriatic arthritis	05/16/2026
fam-trastuzumab deruxtecan	AstraZeneca; Daiichi Sankyo	IV	HER2-positive breast cancer	05/18/2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
insulin recombinant human	MannKind Corporation	INH	Improve glycemic control in type I diabetes and type II diabetes	05/29/2026
lumateperone tosylate	Johnson & Johnson	PO	Long-term relapse prevention in schizophrenic patients	05/2026
guselkumab	Johnson & Johnson	IV; SC	Psoriatic arthritis	05/2026
venetoclax	Roche; Genetech; AbbVie	PO	Chronic lymphocytic leukemia	05/2026
dexmethylphenidate hydrochloride	Cingulate Therapeutics	PO	Attention deficit hyperactivity disorder (ADHD) in adults and children	05/31/2026
vepdegestrant	Pfizer; Arvinas	PO	Breast cancer	06/05/2026
ensitrelvir fumaric acid	Shionogi	PO	Prevention of Coronavirus disease 2019 (COVID-19) exposure	06/16/2026
pneumococcal 21-valent conjugate vaccine	Merck & Co; Ligand Pharmaceuticals	IM	Pneumococcal disease	06/18/2026
nilotinib	Xspray	PO	Chronic myeloid leukemia	06/18/2026
sodium oxybate	Tris Pharma	PO	Narcolepsy; idiopathic hypersomnia (IH)	06/20/2026

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cytisinicline	A chieve Life Sciences	PO	Aid to smoking cessation	06/20/2026
pegadricase	Swedish Orphan Biovitrum; 3SBio Group; Selecta; Cartesian	IV	Gout	06/27/2026
roflumilast	Arcutis	TOP	Plaque psoriasis	06/29/2026
bulevirtide	Gilead; MYR Pharmaceuticals	SC	Hepatitis D	1H 2026
tirzepatide	Eli Lilly	SC	Improve glycemic control in type 2 diabetes	1H 2026
brimonidine tartrate	Sun; Visiox Pharma; SPRAC; Ocuvex	OPHT	Open-angle glaucoma or ocular hypertension	1H 2026
daratumumab; hyaluronidase	Johnson & Johnson; Genmab; Halozyme	SC	Multiple myeloma	1H 2026
orforglipron	Eli Lilly; Chugai	PO	Obesity	1H 2026
camizestrant	AstraZeneca	PO	Hormone receptor positive breast cancer	1H 2026
bupropion hydrochloride; dextromethorphan	Axsome	PO	Agitation in Alzheimer's disease	1H 2026

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teclistamab	Johnson & Johnson	SC	Multiple myeloma	1H 2026
sonrotoclax	BeiGene; BeOne Medicines	PO	Mantle cell lymphoma	2Q 2026
tebipenem pivoxil hydrobromide	GSK; Meiki Seika; Spero Therpeutics	PO	Complicated urinary tract infection (UTI); pyelonephritis	2Q 2026
pivekimab sunirine	AbbVIe; ImmunoGen	IV	Blastic plasmacytoid dendritic cell neoplasm	2Q 2026
baxdrostat	AstraZeneca; CinCor Pharma	PO	Hypertension	2Q 2026
cefepime; zidebactam	Wockhardt	IV	Complicated urinary tract infection (UTI); pyelonephritis	2Q 2026
budesonide; formoterol fumarate; glycopyrrolate	AstraZeneca; Pearl Therapeutics	INH	Asthma	2Q 2026
anifrolumab	AstraZeneca; MedImmune	SC	Systemic lupus erythematosus	2Q 2026
pegargiminase	Phoenix Polaris Group	IM	Mesothelioma	2Q 2026
durvalumab	AstraZeneca; MedImmune	IV	High-risk non-muscle invasive bladder cancer	2Q 2026

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capivasertib	AstraZeneca; Astex Pharmaceuticals	PO	Prostate cancer	2Q 2026
benralizumab	AstraZeneca; MedImmune; Kyowa Kirin	SC	Hypereosinophilic syndrome (HES)	2Q 2026
trenibotulinumtoxinE	Allergan; AbbVie	IM	Glabellar lines	2Q 2026
gadoquatrane	Bayer	IV	For diagnostic MRI	2Q 2026
marstacimab	Pfizer	SC	Hemophilia A or B in patients with inhibitors	2Q 2026
sasanlimab	Pfizer	SC	Bladder cancer	2Q 2026
denosumab-enz215	Alkem Labs; Ascned; Enzene	SC	Increasing bone mass; osteoporosis in men and postmenopausal women; glucocorticoid-induced osteoporosis	2Q 2026
denosumab-enz215	Alkem Labs; Ascned; Enzene	TBD	Hypercalcemia of malignancy; bone metastases; giant cell tumor of bone	2Q 2026
lecanemab	Eisai; Biogen; BioArctic; Neuroscience	SC	Alzheimer's disease	2Q 2026
ranibizumab-lubt	Lupin	IVT	Wet age-related macular degeneration	06/2026

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oxylanthanum carbonate	Spectrum Therapeutics; Unicycive Therapeutics	PO	Hyperphosphatemia in chronic kidney disease	06/2026
trastuzumab-tx05	Tanvex	INJ	HER2 positive breast cancer	06/2026
veligrotug	Viridian Therapeutics	IV	Thyroid eye disease	06/30/2026
manganese chloride tetrahydrate	Ascelia	PO	For diagnostic MRI	07/03/2026
relacorilant	Corcept Therapeutics	PO	Ovarian cancer	07/11/2026
furosemide	MannKind Corporation; scPharmaeuticals	SC	Chronic kidney disease; chronic heart failure	07/26/2026
ethinyl estradiol; norelgestromin	Mylan; Viatris	TD	Pregnancy prevention	07/30/2026
florquinitau	Lantheus Medical Imaging; Cerveau; LuMind IDSC; Engima Biomedical	IV	Alzheimer's disease	08/13/2026
lutetium lu 177 edotreotide	ITM	IV	Gastroenteropancreatic neuroendocrine tumors	08/28/2026
ustekinumab	Johnson & Johnson	SC	Ulcerative colitis	08/2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
ustekinumab	Johnson & Johnson	IV	Ulcerative colitis	08/2026
zidesamtinib	Nuvalent	PO	Non-small cell lung cancer (NSCLC)	09/18/2026
gedatolisib	Pfizer; Celcuity	IV	Hormone receptor positive, HER2(-) breast cancer	3Q 2026
potassium bicarbonate; potassium citrate	Advicenne	PO	Renal tubular acidosis	3Q 2026
atacicept	EMD Serono; ZymoGenetics; Vera Therapeutics	SC	IgA nephropathy	3Q 2026
doruxapapogene ralaplasmid	Inovio	IM	Recurrent respiratory papillomatosis (RRP)	3Q 2026
beclomethasone dipropionate; formoterol fumarate dihydrate	Chiesi	INH	Asthma	3Q 2026
sacituzumab govitecan	Gilead; Immunomedics	IV	Breast cancer	3Q 2026
denecimig	Novo Nordisk; Genmab	SC	Hemophilia A	3Q 2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
apixaban	TAHO	PO (oral dissolving film)	Nonvalvular atrial fibrillation to reduce risk of systemic embolism and stroke	3Q 2026
icotrokinra	Johnson & Johnson	PO	Plaque psoriasis	3Q 2026
omalizumab	Amneal; Kashiv BioSciences	SC	Chronic idiopathic urticaria (CIU)	3Q 2026
tavapadon	Pfizer; AbbVie; Cerevel Therapeutics	PO	Parkinson's disease	3Q 2026
imsidolimab	Vanda Pharmaceuticals; AnaptysBio	IV; SC	Pustular psoriasis	2H 2026
insulin efsitora alfa	Eli Lilly	SC	Improve glycemic control in type 2 diabetes	2H 2026
molgramostim	PARI; Savara; Fujifilm	INH	Pulmonary alveolar proteinosis (PAP)	2H 2026
cyclodextrin	Mallinckrot; Sucampo; Vtesse; Beren; Mandos Health	IT	Niemann-Pick disease Type C	2H 2026
imlifidase	Hansa Biopharma	IV	Desensitization therapy in kidney transplant recipients	2H 2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
olanzapine	Teva; Royalty Pharma; MedinCell	SC	Schizophrenia	4Q 2026
centanafadine	Otsuka	PO	Attention deficit hyperactivity disorder (ADHD)	4Q 2026
cagrilintide; semaglutide	Novo Nordisk	SC	Obesity	4Q 2026