Capital Rx

Medication Pipeline Report 2025 I Q3

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GLOSSARY:

BBW ····· Black-box-warning

FDA ····· Food & Drug Administration

IA ····· Intra-arterial

ID ····· Intradermal

IM ····· Intramuscular

IMP ····· Implant

IN ····· Intranasal

INH ····· Inhaled

INJ ····· Injectable

IT ····· Intrathecal

IUD ····· Intrauterine Device

IV ····· Intravenous

IVT ····· Intravitreal

MRI ····· Medical resonance imaging

OPHT ····· Ophthalmic

OT ····· Otic

PO ····· Oral

REMS ····· Risk Evaluation and Management Strategy

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 Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.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:
9/12/2025

ZEGFROVY™ (SUNVOZERTINIB) PO, DIZAL PHARMACEUTICAL

Approval Date	07/02/2025
Indication	Non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations
Clinical Overview	Lung cancer is the leading cause of cancer death in the US. Non-small cell lung cancer is the most common type of lung cancer with 80-85% of lung cancers being NSCLC. EGFR mutations occur in about 15% of NSCLC adenocarcinomas in the US. The most common cause of lung cancer is smoking tobacco. Symptoms of lung cancer may include lasting cough with/without blood, SOB, weight loss that is unexplained, chest pain, or whistling sounds when breathing out.
Considerations	• FDA granted accelerated approval
Select Alt Therapies	Rybrevant® (amivantamab) IV

LYNOZYFIC™ (LINVOSELTAMAB-GCPT) IV, REGENERON

Approval Date	07/02/2025
Indication	Relapsed or refractory multiple myeloma (MM)
Clinical Overview	MM is a cancer caused by rapid growth of malignant cells in bone marrow. Symptoms of MM can include bone lesions, fatigue, anemia, hypercalcemia, renal dysfunction, or infections. It is the second most common blood cancer with 12,000 deaths anticipated in 2025 within the US. In the United States, 8,000 MM patients are estimated to have progressed to 3 lines of drug therapy.
Considerations	• FDA granted accelerated approval • IV infusion requiring hospitalization 24 hours after the first 2 step up doses • Available only through risk evaluation and mitigation strategy (REMS) program • 5th line therapy for MM
Select Alt Therapies	Talvey® (talquetamab-tgvs) SC, Tecvayli® (teclistamab-cqyv) SC, Elrexfio® (elranatamab-bcmm) SC

EKTERLY® (SEBETRALSTAT) PO, KALVISTA

Approval Date	07/03/2025
Indication	Acute hereditary angioedema (HAE) attacks
Clinical Overview	HAE is a rare genetic disorder caused by excessive bradykinin that causes recurrent and unpredictable attacks of mucosal or subcutaneous swelling without itching. Mutations in the serpin family G member 1 gene can lead to either Type I HAE or Type II HAE. Typically swelling occurs in the hands, feet, airways, or intestinal tract. HAE occurs in 1/10,000 to 1/50,000 individuals.
Considerations	• FDA designated orphan drug • First and only oral on-demand treatment approved for those ≥12 years old
Select Alt Therapies	Firazyr® (icatibant) SC, Berinert® (C1 inhibitor human) IV, Kalbitor® (ecallantide) SC, Ruconest® (conestat alfa) IV

SEPHIENCE™ (SEPIAPTERIN) PO, CENSA PHARMACEUTICALS

Approval Date	07/28/2025
Indication	Hyperphenylalaninemia (patients≥1 month old) with phenylketonuria (PKU)
Clinical Overview	PKU is a rare disorder caused by metabolism error that leads to increase Phe blood levels. PKU is caused by autosomal recessive mutations in the gene that produces phenylalanine hydroxylase (Phe). When Phe builds up in the brain, it can cause central nervous system toxicity which if left untreated can lead to developmental delay, seizures, skin diseases, and permeant intellectual disability. Prevalence of PKU in the US is about 1 in every 25,000 people.
Considerations	• Should be used with a phenylalanine (PHE)-restricted diet • Works intracellularly unlike other similar alternatives
Select Alt Therapies	Kuvan® (sapropterin dihydrochloride) PO, Palynziq® (pegvaliase-pqpz) SC

MODEYSO™ (DORAVIPRONE) PO, CHIMERIX

Approval Date	08/07/2025
Indication	Diffuse midline glioma (DMG) specifically H3 K27M-mutant glioma for pediatrics (≥1 years old) and adults
Clinical Overview	DMG are rare aggressive brain tumors that occur in the central nervous system. This type of brain cancer is mostly seen in pediatric patients and has a low survival rate. H3 K27M-mutant DMG is classified as a Grade IV brain tumor. In the US, about 2,000 patients yearly are affected by the H3 K27M-mutant glioma and the only treatment available is radiotherapy. Radiotherapy only provides temporary relief in these patients, and the median survival is about 1 year from initial diagnosis.
Considerations	• Rare pediatric disease designation • Orphan drug • FDA granted accelerated approval • First systemic therapy for H3 K27M-mutant DMG
Select Alt Therapies	Modeyso™(doraviprone) is the first FDA approved treatment for H3 K27M-mutant DMG. Currently, treatment includes radiotherapy.

HERNEXEOS® (ZONGERTINIB) PO, BOEHRINGER INGELHEIM

Approval Date	08/08/2025
Indication	HER2+ unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC)
Clinical Overview	Lung cancer is the leading cause of US cancer related death. NSCLC is 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. HER2 mutations occur in about 2-4% of patients with NSCLC and are typically found in younger female patients who have never smoked. HER2 mutations have an increased risk of causing brain metastases.
Considerations	• FDA granted accelerated approval • First oral targeted therapy for previously treated HER2-mutant NSCLC
Select Alt Therapies	Enhertu® (fam-trastuzumab deruxtecan) IV

BRINSUPRI™ (BRENSOCATIB) PO, ASTRAZENECA, INSMED

Approval Date	08/12/2025
Indication	Non-cystic fibrosis bronchiectasis (NCFB)
Clinical Overview	NCFB is a respiratory condition that causes the airways to widen and thicken. It involves productive cough, sputum production, airway inflammation, recurrent respiratory infections, and abnormal bronchial infiltration on CT scans. Symptoms consist of fatigue, cough, and shortness of breath. Treatment consists of antibiotics for 10-14 days for infections and airway clearance with hypertonic saline as first line therapy. About 500,000 people in the US have NCFB.
Considerations	• First drug FDA approved for NCFB
Select Alt Therapies	Antibiotics, Acetadote (acetylcysteine) INH

PAPZIMEOS™ (ZOPAPOGENE IMADENOVEC) SC, PRECIGEN

Approval Date	08/14/2025
Indication	Treatment of recurrent respiratory papillomatosis (RRP)
Clinical Overview	RRP is caused by chronic human papillomavirus (HPV) and is a rare disease that causes benign tumor growth in the respiratory tract. The tumors typically develop in the larynx, trachea, and lungs. The tumors are usually surgically removed and require multiple surgical debridement. There are 20,000 cases of RRP that occur per year in the US. The HPV 6 or 11 subtypes are the main subtypes that cause about 90% of RRP cases.
Considerations	• First FDA approved drug for RRP
Select Alt Therapies	Papzimeos ™ (zopapogene imadenovec) is the first FDA-approved treatment for RRP. Currently, IV benacizumab or intralesional cidofovir are used off label, or repeated surgical debridement and debulking.

DAWNZERA™ (DONIDALORSEN) SC, IONIS PHARMACEUTICALS

Approval Date	08/21/2025
Indication	Prophylaxis for hereditary angioedema (HAE) attacks in adults and pediatrics (≥12 years old)
Clinical Overview	HAE is an autosomal dominant genetic disorder that causes recurrent attacks of subcutaneous or mucosal swelling without itching in multiple parts of the body. It is caused by overproduction of bradykinin. Areas of swelling in the body may include hands, face, feet, airways, and intestinal tract. It is a rare disorder with about 1 in every 10,000 to 1 in every 50,000 people being affected in the US.
Considerations	• First therapy that is Prekallikrein (PKK)-directed Antisense Oligonucleotide (ASO) • Extended dosing interval compared to other therapies
Select Alt Therapies	Cinryze® (C1 inhibitor human) IV, Takhzyro® (lanadelumab-flyo) SC, Haegarda® (C1 inhibitor human) SC, Andembry® (garadacimab-gxii) SC, Orladeyo® (berotralstat) PO

WAYRILZ™ (RILZABRUTINIB) PO, SANOFI

Approval Date	08/29/2025
Indication	Persistent or Chronic Immune Thrombocytopenia (ITP)
Clinical Overview	ITP is a rare autoimmune disorder that leads to low platelet counts. Patients with this disorder typically bleed and bruise easily due to the blood not clotting as it should. Other symptoms consist of fatigue, menorrhagia, gastrointestinal bleeding, and increased thrombosis risk. Chronic ITP lasts longer than 12 months and usually effects adults though some of the pediatric population can get this disorder. ITP is rare as it occurs in 2-4 per 100,000 adults.
Considerations	• First BTKA inhibitor for this indication • Orphan drug • Mechanism of action is different than current therapies available and targets root cause of disease
Select Alt Therapies	Nplate® (romiplostim) SC, Doptelet® (avatrombopag) PO, Alvaiz® (eltrombopag) PO, Tavalisse® (fostamatinib) PO

BILPREVDA® (DENOSUMAB-NXXP) SC, HENLIUS, ORGANON

Approval Date	09/02/2025
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	• Biosimiliar of Xygeva®
Select Alt Therapies	Xygeva® (denosumab) SC, Bomyntra® (denosumab-bnht) SC, Osenvelt® (denosumab-bmwo) SC, Wyost® (denosumab-bbdz) SC, Xybrx® (denosumab-dssb) SC

BILDYOS® (DENOSUMAB-NXXP) SC, HENLIUS,ORGANON

Approval Date	09/02/2025
Indication	Increasing bone mass from breast cancer or prostate cancer treatment and osteoporosis for postmenopausal women, men, or glucocorticoid-induced osteoporosis
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	• Biosimilar of Prolia®
Select Alt Therapies	Prolia® (denosumab) SC, Conexxence® (denosumab-bnht) SC, Jubbonti® (denosumab-bbdz) SC, Stoboclo® (denosumab-bmwo) SC, Ospomyv™ (denosumab-dssb)SC

KIRSTY™ (INSULIN ASPART-XJHZ) SC & IV, BIOCON

Approval Date	07/15/2025
Indication	Type 1 and type 2 diabetes
Clinical Overview	Both type 1 and type 2 diabetes are increasing in prevalence. Type 1 diabetes occurs typically in the younger population and is an autoimmune disorder caused by lack of beta cell production from the pancreas. Type 2 diabetes is 90-95% of all diabetes cases. Type 2 diabetes is not an autoimmune disorder and usually occurs later in life. Type 2 diabetes is caused by the body not using insulin properly though the pancreas still produces beta cells. Symptoms of type 1 and type 2 diabetes consist of frequent urination, feeling thirsty or hungry, extreme fatigue, blurry vision, and numbness in hands and feet.
Considerations	• Biosimilar of Novolog®
Select Alt Therapies	Merilog™ (insulin aspart-szjj) SQ, Novolog® (insulin aspart) SC, Humalog® (insulin lispro) SC

ANZUPGO® (DELGOCITINIB) TOP, LEO PHARMA

Approval Date	07/23/2025
Indication	Chronic hand eczema (CHE)
Clinical Overview	CHE is a type of eczema that can involve both the hands and wrists with it being a common inflammatory skin condition. It reoccurs typically for many years, and most episodes last for 3 months or longer. Common symptoms are redness, dryness, scaling, pain, swelling, itching, oozing, fissures, and thickened skin. Risk factors can include chemical irritants, allergens, or frequent hand washing. About two thirds of patients with hand eczema have chronic hand eczema.
Considerations	• First drug FDA approved for CHE • Does not have Boxed Warning like oral JAK inhibitors
Select Alt Therapies	Opzelura® (ruxolitinib) TOP, Vtama® (tapinarof) TOP

VIZZ™ (ACECLIDINE HYDROCHLORIDE) OPHT, LENZ THERAPEUTICS

Approval Date	07/31/2025
Indication	Presbyopia
Clinical Overview	Presbyopia is a gradual decrease in near vision due to aging. It is caused by the crystalline lens of the eyes not being able to round and shape normally for near vision. It is the most common cause of visual impairment in the US with 110 million people being affected by it. 1.8 billion people around the world are affected by presbyopia. It typically starts at age 40 and can worsen over time until age 65.
Considerations	• Once daily administration with a longer duration of action than alternative therapies (10 hours) • Presbyopia is most commonly managed with corrective lenses
Select Alt Therapies	Vuity™ (pilocarpine hydrochloride) OPHT, Qlosi™ (pilocarpine hydrochloride) OPHT, or corrective lenses

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Kerendia® finerenone	Bayer	PO	Heart failure	7/11/2025
Otezla® apremilast	Amgen, Celgene	PO	Pediatric patients (≥6 years old) with psoriatic arthritis or moderate to severe plaque psoriasis	7/23/2025
Vostally® ramipiril	Rosemont Pharmaceuticals	New: PO Solution	Hypertension, heart failure, cardiovascular event risk reduction	7/23/2025
Doptelet® avatrombopag maleate	Swedish Orphan Biovitrum	PO (granules)	Pediatric (1 to <6 years old) immune thrombocytopenia	7/24/2025
Empaveli® pegcetacoplan	Apellis	SC	C3 glomerulopathy, membranoproliferative glomerulonephritis (≥12 years old)	7/28/2025
Skytrofa® lonapegsomatropin	Ascendis Royalty Pharma	SC	Adult growth hormone deficiency	7/28/2025
Sirturo® bedaquiline fumarate	Johnson & Johnson	PO	Treatment of tuberculosis in pediatric patients ≥2 years old	7/28/2025
Avtozma® tocilizumab	Celltrion	IV	Cytokine release syndrome	7/29/2025
Vyscoxa™ celecoxib	Carwin	New: PO suspension	Osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis	7/29/2025
Biktarvy® bictegravir Sodium	Gilead	PO	Alagille syndrome, Pruritus in progressive familial intrahepatic cholestasis HIV-1 infection in pediatric patients ≥14 kg	7/30/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Atmeksi® methocarbamol	Rosemont	PO	Acute musculoskeletal pain	7/30/2025
Alhemo® concizumab	Novo Nordisk	SC	Hemophilia A or B without inhibitors	7/31/2025
Leqvio® inclisiran	Novartis	SC	Reduce LDL-C in adults with hypercholesterolemia	7/31/2025
Phyrago™ dasatinibe	Handa Therap	PO	Pediatric patients ≥1 years old with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia or newly diagnosed Ph+ acute lymphoblastic leukemia	8/1/2025
Ajovy™ fremanezumab	Teva	SC	Prevention of episodic migraine in the pediatric population those 6-17 years old	8/5/2025
Ketarx™ ketamine	PharmaTher	IV	Acute surgical post-operative pain relief	8/8/2025
Wegovy® semaglutide	Novo Nordisk	SC	Non-alcoholic steatohepatitis (NASH)	8/15/2025
Cyklx® articaine hydrochloride	American Genomics	OPHT	Local anesthesia of the eye	8/15/2025
Tonmya™ cyclobenzaprine hydrochloride	Tonix	New: Sublingual PO	Fibromyalgia	8/15/2025
Repatha™ evolocumab	Amgen	SC	Atherosclerotic vascular disease due to increased LDL	8/21/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Camcevi ETM® leuprolide mesylate	Foresee Pharmaceuticals	New: 3-month formulation SC	Prostate cancer	8/25/2025
Leqembi® lecanemab	Eisai Biogen	New: SC	Alzheimer's Disease	8/29/2025
Vonvendi® vonicog alfa	Baxalta, Shire, Takeda	IV	Preventative use in adults with all types of von Willebrand Disease (VWD), perioperative use in children with VWD	9/5/2025
Inlexzo™ gemcitabine	Taris, Bristol-Myers Squibb, John & Johnson	Intravesical	Bladder cancer	9/9/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
sodium pyruvate	Cellular Sciences, EmphyCorp	IN	Idiopathic pulmonary fibrosis, COVID-19	3Q 2025
daratumumab hyaluronidase	Johnson & Johnson	SC	Multiple myeloma	3Q 2025
selumetinib sulfate	Pfizer, Alexion, AstraZeneca, Merck & Co	PO	Neurofibromatosis	2H 2025
talazoparib tosylate	Pfizer, Medivation	PO	Prostate cancer, ovarian cancer	2H 2025
remibrutinib	Novartis	PO	Chronic idiopathic urticaria, relapsing multiple sclerosis, myasthenia gravis, hidradenitis suppurativa	2H 2025
denosumab-bmab-1000x biosimilar	Biocon	TBD	Bone metastases for multiple myeloma and tumors, hypercalcemia of malignancy, giant cell tumor of bone	2H 2025
denosumab-bmab-1000p biosimilar	Biocon	SC	Increasing bone mass in breast cancer and prostate cancer, osteoporosis in men and post-menopausal women, and glucocorticoid-induced osteoporosis	2H 2025
denosumab-tvb-009p biosimilar	Teva	SC	Increasing bone mass in breast cancer and prostate cancer, osteoporosis in men and post-menopausal women, and glucocorticoid-induced osteoporosis	2H 2025
mosunetuzumab	Roche, Genentech	SC	Non-Hodgkin's follicular lymphoma, B-cell lymphoma, and diffuse large B-cell lymphoma	2H 2025
semaglutide	Novo Nordisk	SC	Heart failure in patients with obesity	2H 2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
baloxavir marboxil	Roche, Genentech, Shionogi	PO	Acute uncomplicated influenza	09/2025
chikungunya vaccine	Valneva Austria	IM	Chikungunya	09/2025
bumetanide	Corstasis Therapetuics	IN	Edema when potent diuretic is required	09/14/2025
ruxolitinib phosphate	Incyte	TOP	Atopic dermatitis, prurigo nodularis, vitiligo, hidradenitis suppurativa, seborrheic dermatitis, lichen planus, lichen sclerosis	09/19/2025
nusinersen	Biogen, Ionis Pharmaceuticals	IT	Spinal muscular atrophy	09/22/2025
apitegromab	Scholar Rock	IV	Spinal muscular atrophy	09/22/2025
berahyaluronidase alfa; penbrolizumab	Merch & Co (MSD), Alteogen	SC	Bladder cancer, urothelial cancer, breast cancer, colorectal cancer, cervical cancer, endometrial cancer, gastric cancer, esophageal cancer, gastroesophageal cancer, squamous cell carcinoma, kidney cancer, biliary tract cancer, liver cancer, NSCLC, CSCC, mesothelioma, melanoma, Merkel cell carcinoma, Hodgkin's Lymphoma, PMBCL	09/23/2025
paltusotine	Crinetics Pharmaceuticals	PO	Acromegaly	09/25/2025
copper histidinate	Zydus, Sentynl Therapeutics, Zydus, Cyprium Therapeutics	SC	Menkes Disease	09/30/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
dasatinib	Xspray	PO	Chronic myeloid leukemia; acute lymphocytic leukemia	10/07/2025
lubrinectedin	Jazz Pharmaceuticals PharmMar	IV	Small cell lung cancer	10/12/2025
valacyclovir	Hyloris	PO	Chicken pox, herpes zoster	10/12/2025
roflumilast	Arcutis	TOP	Pediatric (2-5 yo) atopic dermatitis	10/13/2025
tezepelumab	AstraZeneca, Amgen, MedImmune	SC	Chronic rhinosinusitis with nasal polyps	10/19/2025
riboflavin 5'-phosphate	Glaukos	OPTH	Keratoconus	10/20/2025
atropine sulfate	Sydnexis	OPHT	Myopia	10/23/2025
edaravone	Shanghai Auzone	PO	Lou Gehrig's disease	10/23/2025
belantamab mafodotin	Pfizer, GSK, Seagen	IV	Multiple myeloma	10/23/2025
sotatercept	Bristol-Myers Squibb, Celgene, Acceleron	SC	Pulmonary arterial hypertension	10/25/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
revumenib	Syndax	PO	Acute myeloid leukemia	10/25/2025
fosfomycin	Nabriva, Zavante, Meitheal	IV	Pyelonephritis	10/29/2025
guselkumab	Johnson & Johnson	IV, SC	Pediatric: Ulcerative colitis, plaque psoriasis, psoriatic arthritis	10/2025
lumateperone tosylate	Johnson & Johnson	PO	Major depressive disorder	10/2025
semaglutide	Novo Nordisk	SC	Peripheral arterial disease	10/2025
obinutuzumab	Roche, Genentech, Biogen	IV	Lupus nephritis	10/2025
generic: risperidone	Teva MedinCell	SC	Maintenance treatment of bipolar I disorder	10/2025
golimumab	Johnson & Johnson	SC	Pediatric ulcerative colitis, rheumatoid arthritis	10/2025
semaglutide	Novo Nordisk	PO	Reduce cardiovascular mortality in patients with type II diabetes	10/2025
plozasiran	Arrowhead	SC	Familial chylomicronemia syndrome	11/18/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
sibeprenlimab	Otsuka, Visterra	IV, SC	IgA nephropathy	11/28/2025
flibanserin	Sprout	PO	Female sexual dysfunction	11/2025
ziftomenib	Kura Oncology	PO	Acute myeloid leukemia	11/30/2025
navepegritide	Ascendis	SC	Achondroplasia	11/30/2025
lisocabtagene maraleucel	Bristol-Myers Squibb, Celgene, Juno	IV	Marginal zone lymphoma	12/05/2025
mitapivat	Agios	PO	Alpha-thalassemia, beta-thalassemia, non-transfusion-dependent thalassemia	12/07/2025
omidubicel	Gamida Cell Ayrmid	IV	Aplastic anemia	12/10/2025
gepotidacin	GSK	PO	Gonorrhea	12/11/2025
lerodalcibep	LIB	SC	Atherosclerotic vascular risk disease due to hypercholesterolemia, heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia	12/12/2025
berotralstat hydrochloride	BioCryst	PO	Prophylaxis in hereditary angioedema attacks	12/12/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
etripamil	Milestone	IN	Supraventricular tachycardia	12/13/2025
inebilizumab	AstraZeneca, Amgen, MedImmune, Horizon	IV	Myasthenia gravis	12/14/2025
zoliflodacin	AstraZeneca, Innoviva, Entasis	PO	Gonorrhea	12/15/2025
depemokimab	GSK	SC	Eosinophilic asthma, chronic rhinosinusitis with nasal polyps	12/16/2025
reproxalap	AbbVie, Aldeyra	OPTH	Dry eye	12/16/2025
setmelanotide acetate	Rhythm	SC	Hypothalamic obesity	12/20/2025
narsoplimab	Omeros	IV	Thrombotic microangiopathy	12/26/2025
aficamten	Cytokinetics	PO	Hypertrophic cardiomyopathy	12/26/2025
tolebrutinib	Sanofi, Principia Biopharma	PO	Secondary progressive multiple sclerosis, relapsing multiple sclerosis, primary progressive multiple sclerosis, myasthenia gravis	12/28/2025
tradipitant	Vanda	PO	Motion sickness	12/30/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
relacorilant	Corcept	PO	Cushing's syndrome	12/30/2025
denosumab-rgb-14-x biosimiliar	Hikma	SC	Bone metastases for multiple myeloma and tumors, hypercalcemia of malignancy, giant cell tumor of bone	4Q 2025
denosumab-rgb-14-p biosimilar	Hikma	SC	Increasing bone mass in breast cancer and prostate cancer, osteoporosis in men and post-menopausal women, and glucocorticoid-induced osteoporosis	4Q 2025
afilbercept-avto6	Teva, Alvogen, Alvotech	Intravitreal	Wet age-related macular degeneration	4Q 2025
pertuzumab-hlx11 biosimilar	Organon, Henlius	IV	HER2+ breast cancer	4Q 2025
nerandomilast	Boehringer Ingelheim	PO	Interstitial lung disease, idiopathic pulmonary fibrosis	4Q 2025
denosumab-mbo9-p biosimilar	Amneal, Insud Pharma, Fresenius Kabi	SC	Increasing bone mass in breast cancer and prostate cancer, osteoporosis in men and post-menopausal women, and glucocorticoid-induced osteoporosis	4Q 2025
sevabertinib	Bayer	PO	Non-small cell lung cancer	4Q 2025
etuvetidigene autotemcel	GSK, Orchard, Fondazione	IV	Wiskott-Aldrich Syndrome	4Q 2025
durvalumab	AstraZeneca, MedImmune	IV	Gastroesophageal junction cancer, gastric cancer	4Q 2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
elinzanetant	GSK, Bayer, NeRRe	PO	Vasomotor symptoms due to menopause	4Q 2025
imlunestrant	Eli Lilly, Loxo	PO	Breast cancer	4Q 2025
troriluzole	Biohaven, ALS Biopharma	PO	Spinocerebellar ataxia	4Q 2025