Medication Pipeline Report 2025 I Q2

TABLE OF CONTENTS

INTRODUCTION 2

SPECIALTY BRAND APPROVALS 4

NON-SPECIALTY BRAND APPROVALS 12

ADDITIONAL BRAND APPROVALS 14

PRODUCTS IN THE PIPELINE 17

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 Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.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:
6/18/2025

VANRAFIA™ (ATRASENTAN HYDROCHLORIDE) PO NOVARTIS, CHINOOK THERAPEUTICS

Approval Date	04/02/2025
Indication	Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression.
Clinical Overview	IgAN (also known as Berger's disease) is an autoimmune kidney disease in which IgA accumulates and attacks the glomeruli. This impairs the kidney's ability to filter, causing blood and protein to leak into the urine. Because the signs and symptoms of IgAN can be silent or attributed to other conditions, most patients are diagnosed following a respiratory tract illness. The true prevalence of IgAN in the United States is largely unknown but is estimated to be between 130,000 and 150,000 patients, with approximately 30% to 40% of patients having a more progressive form of the disease.
Considerations	BBW: Embryo-Fetal Toxicity • FDA accelerated approval program
Select Alt Therapies	Filspari®(sparsentan) PO, Tarpeyo™ (budesonide) PO; Fabhalta® (iptacopan) PO

JOBEVNE™ (BEVACIZUMAB-NWGD) IV MYLAN, BIOCON, VIATRIS

Approval Date	04/09/2025
Indication	Treatment of patients with metastatic colorectal cancer; Patients with unresectable, metastatic, locally advanced, or recurrent non-squamous non-small cell lung cancer (NSCLC); Recurrent glioblastoma in adults; Metastatic renal cell carcinoma; Persistent, recurrent, or metastatic cervical cancer; Epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Clinical Overview	Colorectal cancer starts in either the colon or the rectum. Due to symptoms of colorectal cancer overlapping with various other conditions, it is not always detected in early stages. Roughly 23% of colorectal cancers are diagnosed after the cancer has metastasized. Non-small cell lung cancer (NSCLC) is one type of cancer that occurs in the lungs and is commonly associated with smoking. Glioblastoma is a type of quick-growing, invasive cancer that is located in the brain or spinal cord. Surgery is a common treatment for glioblastoma, but the cancer commonly grows back within six to nine months, making it recurrent. Renal cell carcinoma is cancer of the kidneys. Roughly 1/3 of renal cell carcinoma metastasizes before it is diagnosed. Cervical cancer is cancer of the cervix and is the fourth most common cancer in women globally. Epithelial ovarian, fallopian tube, and primary peritoneal cancers are all cancers that form in the tissue covering the respective organ, either in the women's reproductive system (ovarian, fallopian tube) or the abdomen (peritoneum).
Considerations	Healthcare administered • Sixth FDA-approved biosimilar of Avastin
Select Alt Therapies	Mvasi®(bevacizumab-awwb) IV, Zirabev™ (bevacizumab-bvzr) IV, Alymsys® (bevacizumab-maly) IV, Vegzelma® (bevacizumab-adcd) IV, Avzivi® bevacizumab-tnjn) IV, Avastin® (bevacizumab) IV

PENPULIMAB-KCQX™ (PENPULIMAB) IV AKESO BIOPHARMA

Approval Date	04/23/2025
Indication	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.
Clinical Overview	Nasopharyngeal carcinoma (NPC) is a type of head and neck cancer that starts in the nasopharynx, the upper part of the throat behind the nose and nasal cavity. NPC is a rare cancer, with less than one case for every 100,000 people in the United States each year. The 5-year relative survival rate is 63% overall, but the cancer can be aggressive. Due to the location of the cancer, surgery is rarely an option
Considerations	Healthcare administered • Assessment Aid Voluntary Submission • Fast-Track Designation
Select Alt Therapies	Loqtorzi™ (toripalimab-tpzi) IV, chemotherapy

ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL) TOP ABEONA THERAPEUTICS

Approval Date	04/28/2025
Indication	Treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa.
Clinical Overview	Epidermolysis bullosa (EB) is a rare skin condition that results in very fragile skin. Due to the skin being so fragile, blisters and open wounds form easily. Blisters and wounds usually start in infancy and lessen with age. In dystrophic EB, scars may form when blisters and wounds heal, resulting in hard skin. When blisters form on the fingers and toes, precautions must be taken to prevent them from joining together. Dystrophic EB is a result of genetics that may cause a reduction in, or complete absence of, an important protein called collagen VII. Collagen VII forms a part of anchoring fibrils, which are present in the skin.
Considerations	First and only autologous cell-based gene therapy for patients with reduced dystrophic epidermolysis bullosa (RDEB) • Only FDA-approved product to treat RDEB wounds with a single application • Expected to be available Q3 2025 • Granted Rare Pediatric Disease Priority Review Voucher by FDA
Select Alt Therapies	Filsuvez® (birch triterpenes) TOP

IMAAVY™ (NIPOCALIMAB-AAHU) IV MOMENTA, JOHNSON & JOHNSON (JANSSEN)

Approval Date	04/28/2025
Indication	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.
Clinical Overview	Generalized myasthenia gravis is a chronic autoimmune condition that results in weakness of skeletal muscle due to antibodies destroying the communication between nerves and muscle. Voluntary muscles are affected by myasthenia gravis, such as muscles in the eyes, mouth, throat, and limbs. Severe complications in myasthenia gravis include difficulty swallowing or breathing. Myasthenia gravis can occur at any age, but onset occurs most commonly in women 20-30 years of age and men over 50 years old.
Considerations	Healthcare administered • FDA Priority Review designation • ·Anti-AChR and anti-MuSK antibody positive individuals comprise ≥90% of the total antibody-positive gMG population
Select Alt Therapies	Vygart® (efartigimod alfa-fcab) IV, Rystiggo® (rozanolixizumab-noli) SQ

AVMAPKI™ FAKZYNJA™ CO-PACK (AVUTOMETINIB; DEFACTINIB) PO PFIZER, ROCHE, CHUGAI, VERASTEM

Approval Date	05/08/2025
Indication	Treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.
Clinical Overview	LGSOC is highly recurrent and less sensitive to chemotherapy. LGSOC is more likely to affect women at different stages in life between the ages of 20 and 30 as well as ages 50 and 60. It affects nearly 80,000 women around the globe and approximately 6,000 to 8,000 women in the U.S. The median survival of a patient affected by LGSOC is 10 years. It is estimated that 30% of patients with LGSOC have a KRAS-mutation.
Considerations	Accelerated Approval • Real-Time Oncology Review pilot program • Assessment Aid Voluntary Submission • Priority Review • Breakthrough Therapy designation • Orphan Drug designation
Select Alt Therapies	Chemotherapy; hormonal therapy

EMRELIS™ (TELISOTUZUMAB VEDOTIN-TLLV) IV ABBVIE

Approval Date	05/14/2025
Indication	Treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression, as determined by an FDA-approved test [≥50% of tumor cells with strong (3+) staining], who have received a prior systemic therapy.
Clinical Overview	NSCLC is a type of lung cancer most commonly associated with smoking and accounts for 85% of all lung cancers. The five-year survival rate for regional NSCLC is 35%, and for metastatic NSCLC, it is 7%. The c-Met receptor is normally expressed at low levels in healthy epithelial cells. When overexpressed, this is a common indicator of the presence of tumor cells in certain cancers, including NSCLC.
Considerations	Healthcare administered • Accelerated Approval • Real-Time Oncology Review pilot program • Assessment Aid Voluntary Submission • FDA also approved the VENTANA MET (SP44) RxDx Assay as a companion diagnostic test for Emrelis™ eligible patients
Select Alt Therapies	traditional chemotherapy

STARJEMZA™ (USTEKINUMAB-HMNY) IV, SQ HIKMA, BIO-THERA SOLUTIONS

Approval Date	05/22/2025
Indication	Treatment of active chronic inflammatory conditions including ulcerative colitis and Crohn's disease
Clinical Overview	Ulcerative colitis (UC) is an inflammatory bowel disease (IBD) that causes inflammation, ulcers, and abdominal pain in the digestive tract. It affects the innermost lining of the rectum and the large intestine. There currently is no cure for UC, but there are interventions that can reduce symptoms and lead to long-term remission. Crohn's disease (CD) is a chronic IBD similar to UC in that it inflames and irritates the digestive tract. CD is most often found in the small intestine and large intestine. There currently is no cure for CD, but it can be managed through medications, surgery, and nutrition.
Considerations	Healthcare administered • Eighth FDA-approved biosimilar for Stelara®
Select Alt Therapies	Stelara® (ustekinumab) IV/SQ, Wezlana™ (ustekinumab-auub) IV/SQ, Selardsi (ustekinumab-aekn) IV/SQ, Pyzchiva® (ustekinumab-ttwe) IV/SQ, Otulfi™ (ustekinumab-aauz) IV/SQ, Imuldosa® (ustekinumab-srlf) IV/SQ, Steqeyma®(Ustekinumab-stba) IV/SQ, Yesintek™ (ustenkinumab-kfce) IV/SQ

IBTROZI™ (TALETRECTINIB) PO ANHEART THERAPEUTICS, DAIICHI SANKYO, NUVATION BIO

Approval Date	06/11/2025
Indication	Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer.
Clinical Overview	Non-small cell lung cancer (NSCLC) is a type of lung cancer, commonly associated with smoking. Some genes have been linked to NSCLC, including ROS1. ROS1-positive NSCLC occurs when the ROS1 gene fuses with part of another gene, causing uncontrolled cell growth and cancer. ROS1-positive NSCLC accounts for up to 2% of lung cancer cases. ROS1-positive NSCLC is often seen in younger patients despite smoking history. ROS1-positive NSCLC is typically aggressive and fast-growing/spreading.
Considerations	Priority Review designation • Breakthrough designation • Assessment Aid Voluntary Submission • Orphan Drug Designation
Select Alt Therapies	Xalkori® (crizotinib) PO, Rozlytrek® (entrectinib) PO, Augtyro™ (repotrectinib) PO

ZUSDURI™ (MITOMYCIN) IVES UROGEN

Approval Date	06/12/2025
Indication	Treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).
Clinical Overview	LG-IR-NMIBC affects 82,000 people in the U.S. every year, and it is estimated that 59,000 of those are recurrent. Transurethral resection of the bladder and intravesical chemotherapy are considered the standard of care. Nearly 70% of NMBIC patients experience at least one recurrence and are more likely to go through further surgeries and chemotherapy. Bladder cancer is primarily present in geriatric populations, with the median age of diagnosis at 73 years of age.
Considerations	First and only FDA approved medication for low-grade intermediate-risk non-muscle invasive bladder cancer • Healthcare administered
Select Alt Therapies	Transurethral resection of the bladder, intravesical chemotherapy

NUVAXOVID™ (COVID-19 VACCINE, ADJUVANTED) IM SANOFI, NOVAVAX, EMERGENT BIOSOLUTIONS

Approval Date	05/16/2025
Indication	Indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older. Individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Clinical Overview	The coronavirus is a common virus that mostly causes sinus infections and is spread the same way as other cold-causing viruses, mostly by infected people coughing, sneezing, or touching - most are not dangerous. According to the World Health Organization (WHO)'s Coronavirus (COVID-19) Dashboard, as of June 2025, there have been 778,050,175 confirmed global cases of COVID-19. According to data from the U.S. Centers for Disease Control and Prevention (CDC), hospitalizations and deaths related to COVID-19 have been trending downward since June 2024 and are occurring at the lowest rates since the start of the pandemic.
Considerations	Healthcare administered
Select Alt Therapies	Spikevax® (Covid-19 vaccine, mRNA) IM, Comirnaty®(Covid-19 vaccine, mRNA) IM

TRYPTYR® (ACOLTREMON OPHTHALMIC SOLUTION) OPHT ACOLTREMON

Approval Date	05/28/2025
Indication	Treatment of the signs and symptoms of dry eye disease.
Clinical Overview	Dry eye disease (DED) is an umbrella term that encompasses many different underlying conditions and pathophysiological mechanisms. Generally, DED can be divided into two major subtypes: aqueous-deficient DED, in which tear secretion is reduced, and evaporative DED, which is caused by the rapid evaporation of tears. DED can be caused by a combination of the two. DED has been diagnosed in about 16.4 million adults in the United States, and up to 37 million experience DED symptoms. Aside from dryness of the eyes, symptoms of DED include stinging, burning, irritation, itchiness, grittiness, redness, blurred vision, light sensitivity, a feeling of a foreign object in the eye, or watery eyes. Beyond the discomfort associated with symptoms, the disease may lead to visual impairment and impact activities of daily living, social and physical functioning, and productivity.
Considerations	Acoltremon is expected to launch the product in Q3 of 2025
Select Alt Therapies	cyclosporine OPHT, Xiidra® (lifitegrast ophthalmic solution) OPHT, Miebo® (perfluorohexyloctane ophthalmic solution) OPHT, Tyrvaya® (varenicline solution) OPHT

MNEXSPIKE® (COVID-19 VACCINE, MRNA) IMMODERNA

Approval Date	05/30/2025
Indication	Indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older. Individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Clinical Overview	The coronavirus is a common virus that mostly causes sinus infections and is spread the same way as other cold-causing viruses, mostly by infected people coughing, sneezing, or touching - most are not dangerous. According to the World Health Organization (WHO)'s Coronavirus (COVID-19) Dashboard, as of June 2025, there have been 778,050,175 confirmed global cases of COVID-19. According to data from the U.S. Centers for Disease Control and Prevention (CDC), hospitalizations and deaths related to COVID-19 have been trending downward since June 2024 and are occurring at the lowest rates since the start of the pandemic.
Considerations	Healthcare administered
Select Alt Therapies	Spikevax® (Covid-19 vaccine, mRNA) IM, Comirnaty®(Covid-19 vaccine, mRNA) IM

WIDAPLIK™ (TELMISARTAN; AMLODIPINE; INDAPAMIDE) PO GEORGE MEDICINES

Approval Date	06/05/2025
Indication	Treatment of hypertension, including initial treatment, to lower blood pressure.
Clinical Overview	Hypertension occurs when the pressure in the blood vessels is too high. It affects an estimated 1.28 billion adults between the ages of 30 and 80. It is estimated that nearly half of those with hypertension are unaware that they are affected due to the absence of obvious symptoms. Some of these could be attributed to other conditions but may present themselves as chest pain, headaches, and blurred vision. Uncontrolled hypertension could lead to heart attacks, strokes, heart failure, kidney failure, and vision loss. Those who are at an increased risk of having hypertension include older adults, those who are obese or overweight, those who lack physical activity, those who have a high-salt diet, and those who overconsume alcohol.
Considerations	BBW: Fetal Toxicity • United States commercial launch is expected in Q4 of 2025 • Only FDA-approved triple combination medication therapy for use as initial therapy
Select Alt Therapies	Zestoretic® (lisianopril; hydrochlorothiazide) PO, Lotrel® (amlodipine benazepril) PO, telmisartan PO, amlodipine PO

ENFLONSIA™ (CLESROVIMAB-CFOR) IM MERCK & CO (MSD)

Approval Date	06/09/2025
Indication	Prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.
Clinical Overview	RSV is a respiratory virus that is transmitted through contact with respiratory droplets of an infected individual and causes infections in the respiratory tract and lungs. RSV can affect individuals of any age but generally causes the most severe infection in infants under 12 months of age, older adults, and immunocompromised individuals. RSV is seasonal in most of the United States, starting in the fall and peaking in the winter. It is estimated that 1-3% of infants under 12 months of age are hospitalized each year in the United States due to RSV.
Considerations	Healthcare administered • Single dose administration • Weight-independent dosing • FDA granted Biologics License Application for Enflonsia™
Select Alt Therapies	Beyfortus™ (niresvimab-alip) IM

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Stelara® ustekinumab	Johnson & Johnson (Janssen), Centocor Biopharmaceutical	IV, SQ	Crohn's disease	04/01/2025
Uplinza® inebilizumab-cdon	AstraZeneca, Amgen, MedImmune, Viela Bio, Horizon Therapeutics	IV	IgG4-related disease	04/03/2025
Sivextro® tedizolid phosphate	Merck & Co (MSD), Cubist Pharmaceuticals, Dong-A Pharmaceuticals, Nabriva	IV, PO	Acute bacterial skin and skin structure infections	04/04/2025
Yuflyma® adalimumab-aaty	Celltrion	SQ	Crohn’s disease	04/07/2025
Amjevita HCF™ adalimumab-atto	Amgen	SQ	Ankylosing spondylitis, Chron’s disease, Ulcerative colitis, Plaque psoriasis, Psoriatic arthritis, Juvenile idiopathic arthritis, Hidradenitis supprativa, Uveitis	04/07/2025
Opdivo® nivolumab	Bristol-Myers-Squibb, Ono Pharmaceutical	IV	Colorectal cancer	04/08/2025
Yervoy® ipilimumab	Bristol-Myers-Squibb	IV	Colorectal cancer	04/08/2025
Lopressor® metoprolol tartrate	Rubicon Research	PO	Hypertension, Angina pectoris, Reduce cardiovascular mortality in myocardial infraction	04/10/2025
Vygart Hytrulo PFS® efgartigimod alfa; hyaluronidase	Argenx	SQ	Chronic inflammatory demyelinating polyneuropathy	04/10/2025
Livmarli® maralixibat chloride	Mirum Pharmaceuticals	PO	Alagille syndrome, Pruritus in progressive familial intrahepatic cholestasis	04/10/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Opdivo® nivolumab	Bristol-Myers-Squibb, Ono Pharmaceutical	IV	Liver cancer	04/11/2025
Yervoy® ipilimumab	Bristol-Myers-Squibb	IV	Liver cancer	04/11/2025
Valtoco® diazepam	Neurelis	IN	Epilepsy	04/15/2025
Mezofy™ aripiprazole	CMG Pharmaceutical	PO	Schizophrenia	04/15/2025
Posfrea™ palonosetron hydrochloride	Dr. Reddy's, Avyxa Pharma	IV	Chemotherapy-induced nausea and vomiting, Post-operative nausea and vomiting	04/16/2025
Eliquis® apixiban	Pfizer, Bristol-Myers-Squibb	PO	Venous thromboembolism	04/17/2025
Dupixent® duilumab	Sanofi, Genzyme, Regeneron	SQ	Chronic idiopathic urticaria	04/18/2025
Qamzova™ meloxicam	Nanjing Delova	INJ	Moderate to severe pain	04/22/2025
Ibrance® palbociclib	Pfizer	PO	Hormone receptive positive breast cancer	04/23/2025
Fylnetra® pegfilgrastim-pbbk	Adello Biologics, Amneal, AE Companies, Kashiv Biosciences	SQ	Patients acutely exposed to myelosuppressive doses of radiation	04/23/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Rinvoq® upadacitinib	AbbVie	PO	Giant cell arteritis	04/28/2025
Releuko® filgrastim-ayow	Amneal, Adello Biologics, AE Companies, Kashiv Biosciences	IV, SQ	Patients acutely exposed to myelosuppressive doses of radiation	04/29/2025
Atzumi™ dihydroergotamine	Satsuma Pharmaceuticals, Shin Nippon Biomedical	IN	Migraine	04/30/2025
Yesintek™ ustekinumab-kfce	Biocon	IV, SQ	Ulcerative colitis, Crohn's disease, Psoriatic arthritis, Plaque psoriasis	04/30/2025
Pyzchiva® ustekinumab-ttwe	Sandoz, Samsung Bioepis	IV, SQ	Ulcerative colitis, Crohn's disease, Psoriatic arthritis, Plaque psoriasis	04/30/2025
Selarsdi™ ustekinumab-aekn	Teva, Alvotech	IV, SQ	Ulcerative colitis, Crohn's disease, Psoriatic arthritis, Plaque psoriasis	04/30/2025
Steqeyma® ustekinumab-stba	Celltrion	IV, SQ	Ulcerative colitis, Crohn's disease, Psoriatic arthritis, Plaque psoriasis	04/30/2025
Otufli® ustekinumab-aauz	Formycon, bioeq, Fresenius Kabi	IV, SQ	Ulcerative colitis, Crohn's disease, Psoriatic arthritis, Plaque psoriasis	04/30/2025
Brekiya® dihydroergotamine mesylate	Amneal	INJ	Cluster headache, Migraine	05/14/2025
Welireg® belzutifan	Merck & Co (MSD), Peloton Therapeutics	PO	Pheochromocytoma, Paraganglioma	05/14/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Zynyz® retifanlimab-dlwr	Incyte, Macrogenics	IV	Anal cancer	05/15/2025
Jivi® coagulation factor VIII	Bayer	IV	Hemophilia A	05/19/2025
Hadlima HC® adalimumab-bwwd	Organon, Samsung Bioepis	SQ	Ankylosing spondylitis, Chron's disease, Ulcerative colitis, Plaque psoriasis, Psoriatic arthritis, Juvenile idiopathic arthritis, Hidradenitis supprativa, Uveitis	05/20/2025
Susvimo™ ranibizumab	Genetech, Roche	IVT, IMP	Diabetic retinopathy	05/21/2025
Zoryve® roflumilast	Arcutis	TOP	Scalp psoriasis	05/22/2025
Nucala® mepolizumab	GSK	SQ	COPD with eosinophilic bronchitis	05/22/2025
Yutrepia™ treprostinil	Liquidia Technologies	INH	Lung diseases-associated pulmonary hypertension, Pulmonary arterial hypertension	05/23/2025
Khindivi™ hydrocortisone	Eton Pharmaceuticals	PO	Adrenocortical insufficiency	05/28/2025
Nubeqa® darolutamide	Bayer, Orion	PO	Prostate cancer	06/03/2025
Xifyrm™ meloxicam	Slayback, Azurity Pharmaceuticals	IV	Moderate to severe pain	06/05/2025

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Brukinsa® zanubrutinib	BeiGene	PO	Chronic lymphocytic leukemia, Follicular lymphoma, Mantle cell lymphoma, Marginal zone lymphoma, Waldenstrom's macroglobulinemia	05/15/2025
mResvia® respiratory syncytial virus vaccine	Moderna	IM	Respiratory syncytial virus	06/12/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
concizumab	Novo Nordisk, Dicerna Pharmaceuticals	SQ	Hemophilia A or B	07/2025
darolutamide	Bayer, Orion	PO	Prostate cancer	07/2025
zongertinib	Boehringer Ingelheim	PO	NSCLC	3Q 2025
daratumumab; hyaluronidase	Johnson & Johnson (Janssen), Genmab, Halozyme Therapeutics	SQ	Multiple myeloma	3Q 2025
finerenone	Bayer	PO	Heart failure	3Q 2025
sunvozertinib	Dizal Pharmaceutical	PO	NSCLC	3Q 2025
avatrombopag maleate	Swedish Orphan Biovitrum (Sobi), AkaRx	PO	Chronic immune thrombocytopenia	3Q 2025
denosumab	Teva	SQ	Breast cancer, Glucocorticoid-induced osteoporosis, Osteoporosis in men, Postmenopausal osteoporosis, Prostate cancer	2H 2025
remibrutinib	Novartis	PO	Chronic idiopathic urticaria	2H 2025
delgocitinib	LEO Pharma, Japan Tobacco	TOP	Atopic dermatitis	2H 2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
mosunetuzumab	Roche, Genetech	SC	Follicular lymphoma	2H 2025
linvoseltamab	Regeneron	IV	Multiple myeloma	07/10/2025
datopotamab deruxtecan	AstraZeneca, Daiichi Sankyo	IV	NSCLC	07/12/2025
glofitamab	Roche, Genetech	IV	Diffuse large B-cell lymphoma	07/20/2025
vusolimogene oderparepvec	Replimune	INJ	Melanoma	07/22/2025
belantamab mafodotin	Pfizer, GSK, Seattle Genetics, Segen	IV	Multiple myeloma	07/23/2025
avatrombopag maleate	AkaRx, Dova Pharmaceutical, Swedish Orphan Biovitrum (Sobi)	PO	Chronic immune thrombocytopenia	07/24/2025
lonapegsomatropin	Royalty Pharma, Ascendis	SQ	Adult growth hormone deficiency	07/27/2025
pegcetacoplan	Apellis	SQ	C3 glomerulopathy, Membranoproliferative glomerulonephritis	07/28/2025
odronextamab	Regeneron	IV	Follicular lymphoma	07/30/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
doxecitine; doxribtimine	Zogenix, Modis Therapeutics, UCB	PO	Thymidine kinase 2 deficiency	08/2025
dordaviprone	Chimerix, Oncoceutics, Jazz Pharmaceuticals	PO	Glioma	08/18/2025
rebisufligene etisparvovec	Abeona Therapeutics, Ultragenyx	IV	Mucopolysaccharidosis type IIIA	08/18/2025
afilbercept	Bayer, Regeneron	IVT	Diabetic retinopathy, Wet age-related macular degeneration, Diabetic macular edema, Macular edema following retinal vein occlusion	08/19/2025
vatiquinone	Edison Pharma, Dainippon, Pharmaceutical, PTC Therapeutics	PO	Friedreich's ataxia	08/19/2025
donidalorsen sodium	Ionis Pharmaceuticals	SQ	Hereditary angioedema	08/21/2025
bevacizumab	Outlook Therapeutics	OPHT	Wet age-related macular degeneration	08/27/2025
zopapogene imadenovec	Precigen	SQ	Human papillomavirus: Recurrent respiratory papillomatosis	08/27/2025
sodium dichloroacetate	Saol Therapeutics	PO	Pyruvate dehydrogenase complex deficiency	08/27/2025
89Zr-DFO-girentuximab	Telix	IV	For diagnostic imaging of the kidney	08/27/2025

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
leuprolide mesylate	Forsee Pharma, Accord, ScinoPharm	SQ, INJ	Prostate cancer	08/29/2025
rilzabrutinib	Sanofi, Principia Biopharma	PO	Immune thrombocytopenia	08/29/2025
lecanemab	Biogen, Eisai, BioArctic Neuroscience	IV, SQ	Alzheimer's disease	08/31/2025
deramiocel	Capricor Therapeutics, Nippon Shinyaku	IV	Duchenne muscular dystrophy	08/31/2025
chikungunya vaccine, live	Valneva Austria	IM	Chikungunya	09/2025
narsoplimab	Omeros	IV, SQ	Thrombotic microangiopathy	09/2025
guselkumab	Johnson & Johnson (Janssen)	IV, SQ	Ulcerative colitis	09/2025