Capital Rx

Medication Pipeline Report

2023 | Q3

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Glossary:

IA — Intra-arterial
ID — Intradermal
IM — Intramuscular
IN — Intranasal
INJ — Injectable
IT — Intrathecal
IV — Intravenous
IVT — Intravitreal
OPHT — Ophthalmic
OT — Otic
PO — Oral
SC — Subcutaneous
TD — Transdermal
TOP — Topical

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 Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.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

The drug pipeline is subject to change: information in this report is current as of **09/26/2023**

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LEQEMBI® (LECANEMAB-IRMB) IM, ASTRAZENECA

Approval Date	07/06/2023
Indication	Treatment of Alzheimer's disease
Clinical Overview	Alzheimer's disease (AD) accounts for 60-80% of dementia cases, making it the leading cause of dementia. AD is a progressive neurodegenerative disease that is irreversible and associated with cognitive, behavioral, and functional impairments. Progressive accumulation of amyloid beta plaques between neurons and neurofibrillary tangles are thought to be the cause of AD.
Considerations	Received accelerated approval on 01/06/2023, traditional approval 07/06/2023 • Healthcare administered • Clinical trials included patients with mild cognitive impairment/dementia stage only
Select Alternative Therapies	Aduhelm® (aducanumab) IV [accelerated approval only], Aricept® (donepezil) PO, Razadyne® (galantamine) PO, Exelon® (rivastigmine) PO, Namenda® (memantine) PO

BEYFORTUS™ (NIRSEVIMAB-ALIP) IM, ASTRAZENECA

Approval Date	07/17/2023
Indication	Prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in all infants under 12 months of age in their first RSV season and pediatric patients up to 24 months of age who remain vulnerable to severe RSV in their second 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 • First monoclonal antibody approved for prevention of RSV in all infants
Select Alternative Therapies	Beyfortus™ is the first monoclonal antibody approved to protect all infants in their first RSV season and vulnerable pediatric patients in their second season. Synagis® (palivizumab) IM injection is available for only a select group of infants 6 months of age or under.

VANFLYTA™ (QUIZARTINIB) PO, DAIICHI SANKYO

Approval Date	07/20/2023
Indication	Treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test, indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy.
Clinical Overview	AML is one of the most common types of leukemia in adult patients. An estimated 20,000 new cases are reported in the United States each year. 30-35% of patients with AML carry the FLT3 mutation, making it the most common mutation in AML. FLT3 is difficult to treat and is associated with a poor prognosis due to quick relapse.
Considerations	Priority review • Orphan drug • REMS drug
Select Alternative Therapies	Rydapt® (midostuarin) PO in combination with cytarabine and daunorubicin induction and cytarabine consolidation, not indicated for maintenance

CYFENDUS™ (ANTHRAX VACCINE ADSORBED, ADJUVANTED) IM, EMERGENT BIOSOLUTIONS

Approval Date	07/20/2023
Indication	Vaccine indicated for post-exposure prophylaxis of anthrax following suspected or confirmed exposure to Bacillus anthracis in patients 18 to 65 years old, administered in conjunction with recommended antibacterial drugs
Clinical Overview	Anthrax disease is a bacterial infection caused by Bacillus anthracis, which occurs naturally in soil, commonly infecting domestic and wild animals. Anthrax disease can occur if an individual comes in contact with an infected animal or contaminated animal products by breathing in spores, ingesting food/water with contaminated spores, or spores enter through a cut in the skin. Anthrax is very uncommon in the United States. However, anthrax can be deadly, with a mortality rate of 20-45%.
Considerations	Healthcare administered • Used in conjunction with antibacterial drugs
Select Alternative Therapies	Biothrax® (anthrax vaccine adsorbed) IM/SC (pre- and post-exposure prophylaxis); the current anthrax treatment consists of antimicrobial therapy and supportive care (+/- adjunctive glucocorticoids), and drainage of pleural effusions for inhalation anthrax

BALFAXAR® (PROTHROMBIN COMPLEX CONCENTRATE (HUMAN) LANS) IV, OCTAPHARMA

Approval Date	07/21/2023
Indication	Urgent reversal of Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure
Clinical Overview	Warfarin causes significant risks perioperatively, such as an increased risk of hemorrhage. Warfarin can be discontinued prior to elective surgeries, but urgent surgeries and procedures pose a unique complication, urgent reversal. Urgent reversal is generally considered INR reduction within 30-60 minutes.
Considerations	Must be reconstituted with sterile water for injection (sWFI) prior to administration • Healthcare administered
Select Alternative Therapies	Kcentra® (Prothrombin Complex Concentrate (Human)) IV, Fresh Frozen Plasma (FFP) IV

IZERVAY™ (AVACINCAPTAD PEGOL) IVT, IVERIC BIO

Approval Date	08/04/2023
Indication	Treatment of geographic atrophy secondary to age-related macular degeneration
Clinical Overview	Geographic atrophy is an advanced form of dry age-related macular degeneration in which areas of the retina experience atrophy. Areas of atrophy can result in a dim or blind spot in vision. 67% of patients lose the ability to drive within 1.6 years and 50% lose two lines of vision within 2 years.
Considerations	Healthcare administered • Intravitreal injection to each affected eye once monthly for up to 12 months
Select Alternative Therapies	Syofovre™ (pegcetacoplan) IVT

TALVEY™ (TALQUETAMAB-TGVS) SC, JANSSEN BIOTECH

Approval Date	08/09/2023
Indication	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
Clinical Overview	Multiple myeloma is cancer of the plasma cells in the bone marrow, with a 5-year relative survival rate of 58%. There is no known way to prevent multiple myeloma from developing since few cases are linked to avoidable risk factors. Almost all myeloma patients experience relapse (cancer returns after successful treatment) and/or the cancer becomes refractory (cancer does not respond to treatment).
Considerations	Accelerated approval • Healthcare administered • Only available through the Risk Evaluation and Mitigation Strategy (REMS) • First-in-class bispecific GPRC5D-directed CD3 T-cell engager
Select Alternative Therapies	Talvey™ is a first-in-class agent. Prior treatment options included various therapy combinations, such as one or more therapies that are typically used in initial treatment or repeat of the initial treatment option. Stem cell transplant following high-dose chemotherapy is an option for some patients. Elfrexfio™ (eltranatamab-bcmm) SC is an alternative therapy that was FDA approved shortly after Talvey™ and is mentioned later in this pipeline report.

AKEEGA™ (NIRAPARIB; ABIRATERONE ACETATE) PO, JANSSEN BIOTECH

Approval Date	08/11/2023
Indication	Treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer
Clinical Overview	Prostate cancer is the most common cancer in American men, aside from skin cancer. Roughly 1 in 8 men will be diagnosed with prostate cancer in his lifetime. Hormone therapy, typically androgen depletion therapy (ADT), alone or in combination with other agents, is generally first line treatment for prostate cancer. Castration-resistant prostate cancer is defined as disease progression after ADT.
Considerations	Priority review • Used in combination with prednisone 10 mg PO daily
Select Alternative Therapies	PARP inhibitor (Lynparza®(olaparib) PO, Rubraca® (rucaparib) PO) monotherapy with continuation of ADT, Zytiga® (abiraterone) PO with prednisone monotherapy, Zytiga® (abiraterone) PO/prednisone in combination with Lynparza® (olaparib) PO or Zejula (niraparib) PO, Talzenna® (talazoparib) PO in combination with Xtandi® (enzalutamide) PO

ELFREXFIO™ (ELTRANATAMAB-BCMM) SC, PFIZER

Approval Date	08/14/2023
Indication	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
Clinical Overview	Multiple myeloma is cancer of the plasma cells in the bone marrow, with a 5-year relative survival rate of 58%. There is no known way to prevent multiple myeloma from developing since few cases are linked to avoidable risk factors. Almost all myeloma patients experience relapse (cancer returns after successful treatment) and/or the cancer becomes refractory (cancer does not respond to treatment).
Considerations	Accelerated review • Breakthrough therapy designation • Orphan drug • Only available through the Risk Evaluation and Mitigation Strategy (REMS)
Select Alternative Therapies	Talvey™ (talquetamab-tgvs) SC

HEPZATO™ KIT (MELPHALAN/HEPATIC DELIVERY SYSTEM [HDS]) IA, DELCATH

Approval Date	08/14/2023
Indication	Liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver.
Clinical Overview	Uveal melanoma is cancer in the middle layer tissues of the eye. Uveal melanoma is a rare cancer and approximately 1,700 people are diagnosed in the United States each year. In recurrent uveal melanoma, liver metastasis develops in roughly 2/3 of patients. The median survival of uveal cancer with liver metastasis is 5 to 7 months.
Considerations	Orphan Drug • Only available through the Hepzato Kit Risk Evaluation and Mitigation Strategy (REMS) • Healthcare administered
Select Alternative Therapies	Hepzato™ Kit (melphalan/hepatic delivery system [HDS]) IA is the only FDA approved liver-directed treatment for uveal melanoma liver metastases. Other treatment options include regional isolation perfusion of the liver, embolization (chemotherapy, radiation, immunotherapy), ablative procedures, resection, or radiation therapy.

SOHONOS™ (PALOVAROTENE) PO, IPSEN

Approval Date	08/16/2023
Indication	Reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP)
Clinical Overview	Fibrodysplasia ossificans progressiva (FOP) is a very rare genetic disorder involving the connective tissue, characterized by abnormal development of bone in areas where bone is not normally present. In FOP, skeletal muscles and soft connective tissue undergo a transformation into bone. This transformation makes movement difficult or impossible. The average lifespan of individuals with FOP is 56 years of age, but most individuals with FOP require partial or complete assistance for movement by age 30.
Considerations	Priority Review • Orphan drug
Select Alternative Therapies	Sohonos™ (palovarotene) PO is the first agent approved for FOP. Other treatment options include corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs).

VEOPOZ™ (POZELIMAB-BBFG) IV/SC, REGENERON

Approval Date	08/18/2023
Indication	Treatment of adult and pediatric patients aged 1 year and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
Clinical Overview	CHAPLE disease is a very rare genetic immune disease that causes the complement system to be overactive and attack the body's own cells. This is due to mutations in CD55 (complement regulator gene). Worldwide, less than 100 people are diagnosed with CHAPLE disease. Complications of CHAPLE disease include severe GI issues, lack of nutrient absorption from diet, lung infections, blood clots, and more.
Considerations	Fast track designation • Orphan drug • First FDA approved agent specifically for CHAPLE disease
Select Alternative Therapies	Veopoz™ (pozelimab-bbfg) IV/SC is the first approved agent for CHAPLE disease. Prior treatment was focused on symptom improvement.

EYELEA® HD (AFLIBERCEPT) IVT, REGENERON

Approval Date	08/18/2023
Indication	Treatment of neovascular (wet) age-related macular degeneration and diabetic macular edema
Clinical Overview	Wet age-related macular degeneration (AMD) is a late, less common type of AMD and causes faster vision loss. It is due to abnormal blood vessels growing in the macula that leak blood or fluid, scarring the macula and leading to central vision loss. It cannot be cured but it can be treated. Diabetic macular edema (DME) is retinal thickening caused by fluid accumulation in the retina and can be present at any level of diabetic retinopathy. DME can result in double or blurred vision, floaters, difficulty seeing colors, and limited vision. DME has no cure but can be treated.
Considerations	Healthcare administered • High dose version of Eylea® IVT
Select Alternative Therapies	Treatment alternatives for wet AMD includes anti-VEGF injections: Beovu® (brolucizumab-dbll) IVT, Eylea® (aflibercept) IVT, Lucentis® (ranibizumab) IVT, Vabysmo® (faricimab-svoa)IVT, and Susvimo™ (ranibizumab) IVT via ocular implant. Treatment alternatives for DME also includes anti-VEGF injections: Beovu® (brolucizumab-dbll) IVT, Eylea® (aflibercept) IVT, and Lucentis® (ranibizumab) IVT.

TYRUKO® (NATALIZUMAB-SZTN) IV, SANDOZ

Approval Date	08/24/2023
Indication	Treatment of relapsing forms multiple sclerosis (MS) and treatment of Crohn's disease (CD), inducing and maintaining clinical response
Clinical Overview	Multiple Sclerosis (MS) is an unpredictable autoimmune disease that causes the immune system to attack the central nervous system (CNS) (brain, spinal cord, and optic nerves). Relapsing MS is a common course of MS, occurring in roughly 85% of MS patients, in which patients will have defined attacks of new or increasing symptoms ("relapse") followed by partial or complete recovery ("remission). MS relapses may prompt a change in treatment. Crohn's disease (CD) is a common autoimmune disease that causes chronic inflammation of the GI tract. CD is a chronic disease that may have patterns of disease flares and remission, with symptoms possibly extending beyond the GI tract. Severe CD complications include anal fissures, fistulas, and strictures. Selecting a treatment option for MS and CD is generally highly dependent on patient and disease factors, as well as medication dosage form preferences, side effects, risks, and cost.
Considerations	Biosimilar to Tysabri® (natalizumab) • REMS drug • Healthcare administered
Select Alternative Therapies	Treatment for relapsing MS includes various IV treatments (Briumvi™ (ublituximab-xiiy) IV, Lemtrada® (alemtuzumab) IV, Novantrone® (mitoxantrone) IV, Ocrevus® (ocrelizumab) IV, Tysabri® (natalizumab) IV, Tyruko® (natalizumab-sztn) IV), injectable treatments, and oral treatments. Treatment options for CD include diet, surgery, aminosalicylates, immunomodulators, and various biologic agents (anti-TNF agents, integrin receptor antagonist agents [Tysabri® (natalizumab) IV, Entyvio® (vedolizumab) IV], and interleukin-12 and -23 antagonist agents).

APHEXDA™ (MOTIXAFORTIDE) SC, BIOLINE RX

Approval Date	09/11/2023
Indication	In combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood collection and subsequent autologous transplantation in patients with multiple myeloma
Clinical Overview	Multiple myeloma is cancer of the plasma cells in the bone marrow, with a 5-year relative survival rate of 58%. Stem cell transplant is a common treatment for multiple myeloma. Autologous stem cell transplants are the treatment standard, but allogeneic transplants are also an option. High-dose chemotherapy is administered before the stem cell transplant can occur, which reduces the number of myeloma cells in the body. In autologous stem cell transplants, the patient's own stem cells are removed from the bone marrow or peripheral blood before the transplant occurs, stored while the patient receives high-dose chemotherapy, and are given back to the patient.
Considerations	Orphan drug • Used in combination with G-CSF
Select Alternative Therapies	Mozobil® (plerixafor) SC in combination with G-CSF

OJJAARA™ (MOMELOTINIB) PO, GLAXOSMITHKLINE

Approval Date	09/15/2023
Indication	Treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia
Clinical Overview	Myelofibrosis (MF) is a rare bone cancer that is characterized by fibrosis in the bone marrow, occurring in 1.5 out of every 100,000 people in the United States each year. MF is a type of chronic leukemia and results in the bone marrow not being able to produce enough healthy blood cells. Anemia occurs in nearly all MF patients over the course of the disease. Myelofibrosis can develop on its own (primary MF) or another bone marrow disease can transform into MF (secondary MF). Life expectancy drastically decreases as risk increases (intermediate and high-risk).
Considerations	Orphan drug
Select Alternative Therapies	Vonjo™ (pacritinib) PO, Jakafi® (ruxolitinib) PO, Inrebic® (fedratinib) PO

YCANTH™ (CANTHARIDIN) TOP, VERRICA

Approval Date	07/21/2023
Indication	Treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older
Clinical Overview	Molluscum contagiosum is an infection caused by poxvirus that results in benign, mild skin lesions that may be itchy, sore, red, and/or swollen. Mollusca can occur anywhere on the body, but rarely occurs on the palms of hands or soles of feet. Molluscum contagiosum resolution usually occurs within 6-12 months but can take up to 4 years.
Considerations	Healthcare administered • Only FDA-approved treatment for molluscum contagiosum
Select Alternative Therapies	Ycanth™ (cantharidin) TOP is the first FDA-approved agent for molluscum, but other non-specific treatment options currently include self-limitation (no treatment), physical removal of lesions and Tagamet® (cimetidine) PO

XDEMVY™ (LOTILANER) OPHT, TARSUS

Approval Date	07/24/2023
Indication	Treatment of Demodex blepharitis in adult patients
Clinical Overview	Demodex blepharitis is an inflammatory eye condition that involves the skin, lash follicles, eyelashes, and sebaceous glands. The condition is caused by Demodex mites, which are commonly found on human skin. Demodex blepharitis is largely underdiagnosed and can lead to scarring and blindness if left untreated.
Considerations	Only FDA-approved treatment for Demodex blepharitis
Select Alternative Therapies	Tea tree oil, eyelid cleansers

RIVIVE (NALOXONE) IN, HARM REDUCTION THERAPEUTICS

Approval Date	07/28/2023
Indication	Emergency treatment of known or suspected opioid overdose
Clinical Overview	Opioid overdose is a persistent public health issue that the United States has been facing for decades. It is a complex crisis and public health concern that federal organizations are continuing to address. Between October 2021 and October 2022, more than 101,750 fatal overdoses were reported in the United States. Approving over-the-counter opioid overdose reversal agents (naloxone) increases access to a medication that can help save many lives.
Considerations	Over the counter (OTC)
Select Alternative Therapies	Narcan® (naloxone) IN

ZURZUVAE™ (ZURANOLONE) PO, SAGE THERAPEUTICS

Approval Date	08/04/2023
Indication	Treatment of postpartum depression (PPD) in adults
Clinical Overview	Postpartum depression (PPD) is a serious and potentially life-threatening form of depression that occurs after childbirth or in later stages of pregnancy. PPD is characterized by sadness, loss of interest in activities, guilt, and decreased ability to feel pleasure. Severe PPD can cause thoughts of self-harm or thoughts of harming the child, as well as disrupt the maternal-infant bond.
Considerations	Received priority review • First FDA approved oral medication to treat PPD • Should be administered with 400 – 1,000 calories of food, containing 25-50% fat • 14-day treatment course
Select Alternative Therapies	Zulresso® (brexanolone) IV, oral antidepressants

FOCINVEZ™ (FOSAPREPITANT) IV, SPES PHARMACEUTICALS

Approval Date	08/22/2023
Indication	Prevention of, in combination with other antiemetic agents, acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin, and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) in patients 6 months of age and older.
Clinical Overview	Chemotherapy-induced nausea and vomiting (CINV) is a common adverse effect of many chemotherapy regimens and is something that most cancer patients will face. CINV not only affects quality of life but can affect treatment outcomes as well. Acute CINV occurs within minutes to hours of chemotherapy administration and resolves within 24 hours. Delayed CINV occurs >24 hours of chemotherapy administration and may last up to 5 days.
Considerations	Healthcare administered • 505b2 approval pathway • New fosaprepitant dosage form
Select Alternative Therapies	Aprepitant PO/IV, rolapitant PO/IV

EXXUA™ (GEPIRONE) PO, MISSION PHARMACAL

Approval Date	09/22/2023
Indication	Treatment of major depressive disorder (MDD) in adults
Clinical Overview	Major depressive disorder (MDD) is a common mental disorder that can affect individuals of any age. An estimated 280 million people worldwide have depression. MDD has many symptoms, including loss of pleasure or interest in activities, feelings of guilt and/or hopelessness, low energy, and more. Severe MDD can cause thoughts about dying or suicide, self-harm, or suicide.
Considerations	Second azapirone agent approved by the FDA • Extended-release tablets • Dose titration recommended
Select Alternative Therapies	Buspirone is the only other FDA approved azapirone agent. Selective serotonin reuptake inhibitors (SSRIs), (serotonin and norepinephrine reuptake inhibitors (SNRIs), and various antidepressants are also currently used to treat MDD.

LIKMEZ™ (METRONIDAZOLE) PO, APPILI THERAPEUTICS

Approval Date	09/22/2023
Indication	Treatment of trichomoniasis in adults, amebiasis in adults and pediatric patients, and anaerobic bacterial infections in adults
Clinical Overview	Metronidazole is a commonly used oral antibiotic for a variety of conditions, such as trichomoniasis, vaginal infections, skin infections, and more. Metronidazole is one of the mainstay treatment options for anaerobic bacterial infections. It is only available as a tablet form, which has a bitter metallic taste, which raises concern for patients with dysphagia and risks associated with compounding.
Considerations	First and only commercially available metronidazole oral liquid
Select Alternative Therapies	metronidazole tablets PO

ADDITIONAL BRAND APPROVALS

BRAND NAME *(generic name)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Nucynta® *Tapentadol*	Collegium	PO	Acute pain management in pediatric population	07/03/2023
Leqvio® *Inclisiran*	Novartis	SC	Hyperlipidemia in patients who have an increased risk of heart disease (HTN, DM) and have not yet had a first CV event	07/07/2023
Hadlima™ *Adalimumab-bwwd*	Organon	SC	Uveitis	07/11/2023
Amjevita™ *Adalimumab-atto*	Amgen	SC	Uveitis	07/12/2023
Opill® *Norgestrel*	Perrigo	PO	Contraception – Rx to OTC Switch	07/13/2023
Veklury® *Remdesivir*	Gilead	IV	Treatment of COVID-19 without regard of renal impairment, including patients with GFR less than 30 and dialysis	07/13/2023
Eligard® *Leuprolide acetate*	Tolmar	SC	Advanced prostate cancer	07/20/2023
Gavreto® *Pralsetinib*	Genentech	PO	INDICATION REMOVED: RET-mutant medullary thyroid cancer (MTC)	07/20/2023

ADDITIONAL BRAND APPROVALS

BRAND NAME *(generic name)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Wegovy® *Semaglutide*	Novo Nordisk	SC	1.7 mg once weekly can be used as a maintenance dose in patients who do not tolerate the 2.4 mg once weekly dosage	07/21/2023
Jemperli *Dostarlimab-gxly*	GlaxoSmithKline	IV	Primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) or microsatelittle instability-high (MSI-H), in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent	07/31/2023
Lonsurf® *Trifluridine/tipiracil*	Taiho	PO	Combination treatment with bevacizumab for metastatic colorectal cancer	08/02/2023
Prevymis® *Letermovir*	Merck	PO/IV	Prophylaxis of late CMV through 200 days post-HSCT	08/02/2023
Ezallor Sprinkle™ *Rosuvastatin*	Sun Pharmaceuticals	PO	Reduce risk of stroke, MI, and arterial revascularization procedures in adults with established CVD and at least one additional CV risk factor; heterozygous familial hypercholesterolemia (HeFH) in patients 8 years and older	08/04/2023
Daxxify® *DaxibotulinumtoxinA-lanm*	Revance	IM	Cervical dystonia	08/11/2023
Abrilada™ *Adalimumab-afzb*	Pfizer	SC	Uveitis	08/16/2023
Ingrezza® *Valbenazine*	Neurocrine Biosciences	PO	Chorea associated with Huntington's disease	08/18/2023
Abrysvo™ *Respiratory Syncytial Virus vaccine*	Pfizer	IM	Pregnant individuals 32-36 weeks gestational age to prevent disease and severe disease in infants from birth to 6 months of age	08/21/2023
Reblozyl® *Luspatercept-aamt*	Celgene	SC	Anemia in ESA-naïve adult patients with low- to intermediate-risk MDS who require regular RBC transfusions	08/28/2023

ADDITIONAL BRAND APPROVALS

BRAND NAME *(generic name)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Tafinlar® *Dabrafenib*	Novartis	PO	BRAF V600E mutation-positive unresectable or metastatic solid tumors	08/31/2023
Mekinist® *Trametinib*	Novartis	PO	BRAF V600E mutation-positive unresectable or metastatic solid tumors	08/31/2023
Xalkori® *Crizotinib*	Pfizer	PO	New formulation (pellets)	09/07/2023
Comirnaty® *COVID-19 vaccine, mRNA*	Pfizer	IM	Updated 2023-2024 formula	09/11/2023
Spikevax *COVID-19 vaccine, mRNA*	Moderna	IM	Updated 2023-2024 formula	09/11/2023
Temodar® *Temozolomide*	Merck	PO/IV	Adjuvant treatment of newly diagnosed anaplastic astrocytoma	09/14/2023
Jardiance® *Empagliflozin*	Boehringer Ingelheim	PO	Reduce risk of sustained decline in eGFR, ESRD, cardiovascular death, and hospitalization in adults with CKD at risk of progression	09/21/2023

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(generic name)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
Nyxol *Phentolamine*	Ocuphire	OPHT	Mydriasis	09/28/2023
BBI-4000 *Sofpironium bromide*	Brickell Biotech	TOP	Axillary hyperhidrosis	09/2023
Entyvio® *Vedolizumab*	Takeda	SC	Ulcerative Colitis	09/2023
Lebrikizumab	Genentech	SC	Atopic dermatitis	Q3 2023
DCR-PHXC *Nedosiran*	Dicerna	SC	Primary hyperoxaluria	Q3 2023
ATB200 *Cipaglucosidase Alfa*	Amicus	IV	Pompe disease	Q3 2023
AT2221 *Miglustat*	Amicus	PO	Pompe disease	Q3 2023
Bimzelx *Bimekizumab*	UCB	SC	Plaque psoriasis	Q3 2023
Cosentyx® *Secukinumab*	Novartis	SC	Hidradenitis suppurativa	Q3 2023
SVT-15473 *Clobetasol propionate*	Laboratorios Salvat	OPHT	Post-operative inflammation and pain	Q3 2023
Onpattro *Patisiran*	Alnylam	IV	Transthyretin amyloid cardiomyopathy (ATTR-CM)	10/08/2023
AVT04 *Ustekinumab*	Alvotech	SC	Plaque psoriasis (biosimilar)	10/11/2023
Opdivo® *Nivolumab*	Bristol-Myers Squibb	SC	Melanoma	10/13/2023
Keytruda® *Pembrolizumab*	Merck	IV	Non-small cell lung cancer (NSCLC)	10/16/2023
Combogesic® *Acetaminophen; Ibuprofen*	AFT	IV	Post-operative pain (new route)	10/17/2023
Xphozah *Tenapanor*	Ardelyx	PO	Hyperphosphatemia in CKD	10/17/2023
IDP-126 *Adapalene; benzoyl peroxide; clindamycin*	Bausch	TOP	Acne vulgaris	10/20/2023

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(generic name)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
CSF-1 *Pilocarpine*	Orasis	OPHT	Presbyopia	10/22/2023
Dupixent® *Dupilumab*	Regeneron	SC	Chronic idiopathic urticaria (CIU)	10/22/2023
Zynreleft *Bupivacaine; meloxicam*	Heron	INJ	Post-operative pain	10/23/2023
VBP15 *Vamorolone*	ReveraGen	PO	Duchenne muscular dystrophy	10/26/2023
PF-06886992 *Meningococcal vaccine*	Pfizer	INJ	Meningococcal disease	10/2023
TX01 *Filgrastim*	Tanvex	INJ	Severe chronic neutropenia (biosimilar)	10/2023
BAT1806 *Tocilizumab*	Biogen	IV	Rheumatoid arthritis (biosimilar)	10/2023
Exparel® *Bupivacaine*	Pacira	IT	Post-operative pain (IT)	11/13/2023
Defencath *Taurolidine; heparin*	CorMedix	Catheter lock	Catheter related bloodstream infections	11/15/2023
Vonoprazan	Takeda	PO	Erosive esophagitis	11/17/2023
ADX-102 *Reproxalap*	Aldeyra	TOP; OPHT	Dry eye	11/23/2023
Nirogacestat	Pfizer	PO	Desmoid tumors/aggressive fibromatosis	11/27/2023
TPX-0005 *Repotrectinib*	Bristol-Myers Squibb	PO	Non-small cell lung cancer (NSCLC)	11/27/2023
HMPL-013 *Fruquintinib*	Takeda	PO	Colorectal cancer	11/30/2023
VLA1553 *Chikungunya vaccine*	Valneva	IM	Chikungunya	11/2023
Exa-cel *Exagamglogene autotemcel*	CRISPR	IV	Sickle cell disease	12/08/2023
NurOwn *Debamestrocel*	BrainStorm Cell Therapeutics	IT	Lou Gehrig's disease (ALS)	12/08/2023
Cresemba® *Isavuconazium sulfate*	Astellas	PO; IV	Invasive aspergillosis; invasive mucormycosis	12/09/2023

Livmarli® *Maralixibat*	Mirum	PO	Progressive familial intrahepatic cholestasis (PFIC)	12/13/2023
Keytruda® *Pembrolizumab*	Merck	IV	Gastric cancer; gastroesophageal junction cancer	12/16/2023
Xhance® *Fluticasone propionate*	Optinose	IN	Chronic rhinosinusitis	12/16/2023
ARQ-154 *Roflumalist*	Arcutis	TOP	Seborrheic dermatitis of the scalp	12/16/2023
Abecma® *Idecabtagene*	Bristol-Myers Squibb	IV	Multiple myeloma	12/16/2023
ACT-132577 *Aprocitentan*	Janssen	PO	Hypertension	12/19/2023
Lovo-cel *Lovotibeglogene autotemcel*	BlueBird Bio	IV	Sickle cell disease	12/20/2023
Tarpeyo *Budesonide*	Pharmalink	PO	IgA nephropathy	12/20/2023
Duvyzat *Givinostat*	Italfarmaco	PO	Duchenne muscular dystrophy	12/21/2023
Vabysmo® *Faricimab-svoa*	Roche	IVT	Macular edema following retinal vein occlusion	12/22/2023
G2TR *Travoprost*	Glaukos	OPHT	Open-angle glaucoma or ocular hypertension	12/22/2023
AKCEA-TTR-LRx *Eplontersen*	AstraZeneca	SC	Familial amyloid polyneuropathy	12/22/2023
Lumakras® *Sotorasib*	Amgen	PO	Non-small cell lung cancer (NSCLC)	12/24/2023
MK-7264 *Gefapixant*	Merck	PO	Refractory chronic cough	12/27/2023
Dasiglucagon Continuous Infusion *Dasiglucagon*	Zealand	SC	Congenital hyperinsulinism	12/30/2023
Tibsovo® *Ivosidenib*	Agios	PO	Myelodysplastic Syndromes	12/2023
GL-GLA *Insulin glargine*	Gan & Lee	SC	Improve glycemic control in type 1/type 2 diabetes (biosimilar)	12/2023
LNP023 *Iptacopan*	Novartis	PO	Paroxysmal nocturnal hemoglobinuria	12/2023
Zercepac *Trastuzumab*	Accord	IV	HER2-positive breast cancer; gastric cancer; gastroesophageal junction cancer (biosimilar)	12/2023

PRODUCTS IN THE PIPELINE

GP2411 *Denosumab*	Sandoz	SC	Bone cancer; breast cancer; multiple myeloma; osteoporosis; prostate cancer; tumors on bone metastases; giant cell tumor of bone (biosimilar)	12/2023
RA101495 *Zilucoplan*	UCB	SC	Myasthenia gravis	Q4 2023
Remsima SC *Infliximab*	Celltrion	SC	Crohn's disease; ulcerative colitis (biosimilar)	Q4 2023
SVT-15652 *Clotrimazole*	Laboratorios Salvat	OT	Acute otitis externa	Q4 2023
Braftovi® *Encorafenib*	Pfizer	PO	Non-small cell lung cancer (NSCLC)	Q4 2023
Wilate® *Coagulation Factor VIII (Human)*	Octapharma	IV	Von Willebrand disease	Q4 2023
TAK-755 *Apadamtase alfa; cinaxadamtase alfa*	Takeda	IV	Thrombotic thrombocytopenic purpura	Q4 2023
AZD5363 *Capivasertib*	AstraZeneca	PO	Hormone receptor positive breast cancer	Q4 2023
LUM015 *Pegulicianine*	Lumicell	IV	Diagnostic imaging of the breast	Q4 2023
Mektovi® *Binimetinib*	Pfizer	PO	Non-small cell lung cancer (NSCLC)	Q4 2023
Donanemab	Eli Lilly	IV	Alzheimer's disease	Q4 2023
Jaypirca™ *Pirtobrutinib*	Eli Lilly	PO	Chronic lymphocytic leukemia (CLL)	Q4 2023
LY3074828 *Mirikizumab*	Eli Lilly	IV; SC	Ulcerative colitis	Q4 2023
Xtandi® *Enzalutamide*	Astellas	PO	Prostate cancer	Q4 2023
LY3298176 *Tirzepatide*	Eli Lilly	SC	Obesity	Q4 2023
Zoryve® *Roflumilast*	Arcutis	TOP	Plaque psoriasis	Q4 2023