Capital Rx

Medication Pipeline Report

2021 - Q3 & Q4

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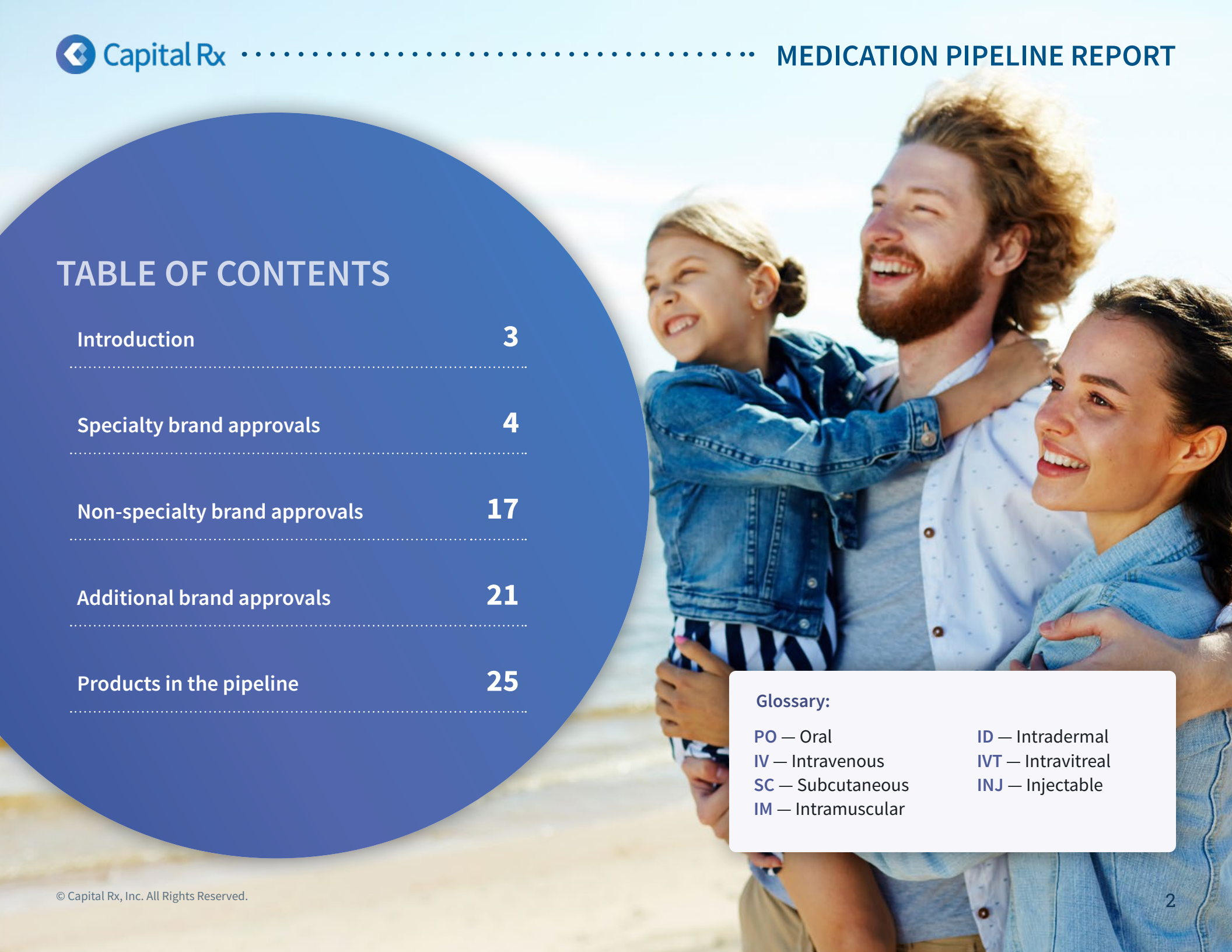

Glossary:

PO — Oral
IV — Intravenous
SC — Subcutaneous
IM — Intramuscular
ID — Intradermal
IVT — Intravitreal
INJ — Injectable

This quarterly Capital Rx Pipeline Report is developed by clinical pharmacists and is prepared using a wide range of clinical resources. The report is designed to keep you up to date on the latest drug approvals and 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 partners the tools and resources they desire.

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The drug pipeline is subject to change: information in this report is current as of 01/05/2022

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ADUHELM IV (ADUCANUMAB-AVWA), *IV,* BIOGEN, EISAI, NEURIMMUNE

Indication	Treatment of early Alzheimer's disease (AD), also referred to as mild cognitive impairment due to AD.
Approval Date	07/07/2021
Clinical Overview	Alzheimer's disease is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out simple tasks. Ultimately, patients lose the ability to communicate and care for themselves, and generally become bedbound. AD is the most common cause of dementia. An estimated 4.5 million people in the U.S. have mild cognitive impairment due to AD.
Considerations	Healthcare administered • Accelerated approval pathway • First therapy to target the fundamental pathophysiology of Alzheimer's disease • 10 out of 11 Peripheral and Central Nervous System Drugs Advisory Committee panel members voted against approval due to insufficient evidence of efficacy in clinical trials
Alternative Therapies	There are currently no approved therapies for this indication and current symptomatic therapies are indicated for patients with established AD dementia.

REZUROCK (BELUMOSUDIL), *ORAL*, KADMON PHARMACEUTICALS

Indication	Treatment of adult and pediatric patients ≥ 12 years of age with chronic graft-versus-host disease (cGVHD) after the failure of at least 2 prior lines of systemic therapy.
Approval Date	07/16/2021
Clinical Overview	Graft-versus-host disease (GVHD) is a common complication following allogeneic hematopoietic stem cell transplantation (HSCT) and occurs when immune cells transplanted from a non-identical donor (graft) recognize the transplant recipient (host) as foreign. Chronic GVHD (cGVHD) is the leading cause of death and complications in patients following allogeneic HSCT. The high mortality rate in cGVHD is likely due to current immunosuppressive treatment modalities in which recurrent infections are common. It is estimated that there are approximately 10,000 allogeneic transplants performed in the United States every year, with 50% of patients developing cGVHD. Prednisone is usually chosen as the initial therapy, but at least 50% of cGVHD patients will require at least 2 lines of therapy.
Considerations	Priority review • Orphan designation
Alternative Therapies	Imbruvica (ibrutinib) PO Jakafi (ruxolitinib) PO

BYLVAY (ODEVIXIBAT), *ORAL*, ALBIREO PHARMA, INC.

Indication	Treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
Approval Date	07/20/2021
Clinical Overview	Progressive Familial Intrahepatic Cholestasis (PFIC) is an ultra-rare group of genetic disorders that disrupt bile formation. PFIC usually develops in infancy, although it can develop into young adulthood, and is characterized by cholestasis, jaundice, and intense pruritus. Most patients with PFIC require biliary diversion surgery or liver transplant by 30 years of age. Albireo estimates that there are approximately 600 cases of PFIC in the United States. PFIC is categorized by type, depending on the patient's genetic mutation. Types 1–3 are the most common, and additional types are still being discovered. While prognosis and disease progression are highly variable, in general, types 1 and 2 are the most severe. The labeled indication includes the limitation that Bylvay may not be effective in PFIC type 2 patients with ABCB11 variants.
Considerations	Priority Review • Orphan designation • Bylavy will be available through three specialty pharmacies: Accredo, Optum Frontier, and PANTHERx Rare pharmacies • Odevixibat is also in Phase 3 trials for Alagille syndrome (ALGS) and biliary atresia
Alternative Therapies	Imbruvica (ibrutinib) PO Jakafi (ruxolitinib) PO

UPTRAVI (SELEXIPAG), *IV*, ACTELION, JANSSEN, JNJ

Indication	Pulmonary arterial hypertension in patients who are temporarily unable to take oral therapy.
Approval Date	07/29/2021
Clinical Overview	Pulmonary arterial hypertension (PAH) is a specific form of pulmonary hypertension that causes the walls of the pulmonary arteries (blood vessels leading from the right side of the heart to the lungs) to become thick and stiff, narrowing the space for blood to flow, and causing an increased blood pressure to develop within the lungs. PAH is a serious, progressive disease with a variety of etiologies and has a major impact on patients' functioning as well as their physical, psychological and social wellbeing. There is currently no cure for PAH and it is often fatal.
Considerations	Healthcare administered • Orphan designation • Avoid short-term treatment interruptions in patients temporarily unable to take oral therapy
Alternative Therapies	Uptravi (selexipag) PO

SAPHNELO (ANIFROLUMAB-FNIA), *IV*, MEDIMMUNE, ASTRAZENECA

Indication	Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.
Approval Date	07/30/2021
Clinical Overview	Systemic lupus erythematosus (SLE) is a chronic autoimmune disease that causes inflammation and organ damage throughout the body. Untreated SLE can lead to permanent damage in organs such as the brain, lungs, and kidneys. The reported prevalence of SLE in the United States is between 20 and 150 per 100,000. Women of childbearing age (15–44 years) are at the greatest risk of developing this autoimmune disease. SLE prevalence is higher in women compared to men, ranging from a female-to-male ratio of 7:1 to 15:1 among adults and 3:1 in children. SLE prevalence is higher among minority racial and ethnic groups, including Asians, African Americans, African Caribbeans, and Hispanic Americans compared to Caucasians. An estimated 28% of patients have moderate-to-severe disease.
Considerations	Healthcare administered • AstraZeneca is currently investigating subcutaneous (SC) delivery of Saphnelo as well as its use in lupus nephritis
Alternative Therapies	hydroxychloroquine PO Benlysta (belimumab) IV, SC

NEXVIAZYME (AVALGLUCOSIDASE ALFA-NGPT), *IV*, SANOFI GENZYME

Indication	Treatment of patients 1 year of age and older with late-onset Pompe disease.
Approval Date	08/06/2021
Clinical Overview	Pompe disease, also referred to as acid maltase deficiency (AMD) or glycogen storage disease type II (GSDII), is an autosomal recessive disorder caused by a deficiency of the lysosomal enzyme acid-α-glucosidase (GAA). All patients with the disease experience a steady accumulation of, and severity/degree of muscle involvement. The incidence of Pompe disease is estimated to be 1:40,000 births in the United States. Glycogen substrate in target tissues leading to progressive debilitation, organ failure and/or death. The severity of the disease varies based on the age of onset, organ involvement and rate of progression. There are approximately 3,500 patients in the United States with Pompe disease, according to the manufacturer.
Considerations	Breakthrough Therapy & Fast Track designations • Healthcare administered
Alternative Therapies	Lumizyme (alglucosidase alfa) IV

WELIREG (BELZUTIFAN), *ORAL*, MERCK & CO, INC.

Indication	Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
Approval Date	08/13/2021
Clinical Overview	Von Hippel-Lindau (VHL) disease is an autosomal-dominant genetic condition resulting from a deletion or mutation in the VHL gene. VHL disease affects about 1 in 36,000 people (10,000 cases in the United States) and 20% of patients are first-in-family or de novo cases. The mean age of onset is 26 years, and 97% of people with a VHL gene mutation display symptoms by 65 years of age. VHL disease affects males and females and all ethnic groups equally. People with this condition may experience tumors and/or cysts in different parts of the body, including the brain, spine, eyes, kidneys, pancreas, adrenal glands, inner ears, reproductive tract, liver, and lung.
Considerations	Ongoing studies of Welireg in other types of RCC and other types of tumors
Alternative Therapies	There is no FDA-approved systemic medications for CNS hemangioblastomas. Votrient (pazopanib) and Sutent (sunitinib malate) have been studied in CNS hemangioblastomas and shown to have limited efficacy. However, Sutent and Votrient are currently being studied specifically in patients with VHL-associated RCC. It is thought that therapy with vascular endothelial growth factor (VEGF)–targeted agents could decrease the size of RCC lesions.

KORSUVA (DIFELIKEFALIN), *IV*, CARA THERAPEUTICS, VIFOR PHARMA

Indication	Treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).
Approval Date	08/23/2021
Clinical Overview	Pruritus is a common and a distressing symptom in patients with chronic kidney disease. Epidemiologic data suggest that approximately 40% of patients with end-stage renal disease experience moderate to severe pruritus and that uremic pruritus (UP) has a major clinical impact because it is strongly associated with poor quality of life, impaired sleep, depression, and increased mortality.
Considerations	Administered at the end of each dialysis session • Healthcare administered
Alternative Therapies	There are currently no approved therapies for this indication.

SKYTROFA (LONAPEGSOMATROPIN-TCGD), *SC*, ASCENDIS PHARMA

Indication	Treatment of pediatric patients 1 year of age and older who weigh at least 11.5 kg (25.4 lb) and have growth failure due to inadequate secretion of endogenous growth hormone.
Approval Date	08/25/2021
Clinical Overview	Growth hormone deficiency (GHD) is a rare disorder that occurs when the pituitary gland does not make enough growth hormone. The condition can occur at any age, some children are born with GHD while others develop it later in life (acquired). Prevalence and incidence data on growth hormone deficiency (GHD) vary widely because of a lack of standard diagnostic criteria. Congenital GHD and most cases of idiopathic GHD are thought to be present from birth, but diagnosis is often delayed until a patient's short stature is observed in relation to their peers. Most types of GHD affect males and females equally, with the exception of GHD III, which affects only males. Since the mid-1980s, children with GHD have typically been treated with somatropin (recombinant human GH [rhGH]) injections, which have been proven to be safe and provide children with the potential to reach normal adult height.
Considerations	Biologic Data Exclusivity • Orphan Drug
Alternative Therapies	The FDA has approved the first sustained release somatropin (growth hormone) product. The FDA has also approved the use of numerous brands of somatropin for pediatric GHD: Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton.

EXKIVITY (MOBOCERTINIB), *ORAL*, TAKEDA

Indication	Treatment of adult patients with locally advanced or metastatic non–small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed on or after platinum-based.
Approval Date	09/15/2021
Clinical Overview	An estimated 1.8 million people are diagnosed with lung cancer worldwide each year. Non–small cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for about 85% of all lung cancer diagnoses. Approximately 2–3% of patients have EGFR exon 20 insertion mutations, which are the third most common type of EGFR mutation. Patients with the EGFR exon 20 insertion mutation have a worse prognosis than those with other EGFR mutations. Each year, an estimated 2,000–4,000 people in the United States are diagnosed with an EGFR exon 20 insertion mutation.
Considerations	Priority review • Breakthrough Therapy, Fast Track, and Orphan Drug designations • Currently in Phase 3 study for first-line treatment
Alternative Therapies	Rybrevant (amivantamab-vmjw) IV

LIVMARLI (MARALIXIBAT), *ORAL*, MIRUM PHARMACEUTICALS, INC.

Indication	Treatment of cholestatic pruritus associated with Alagille syndrome.
Approval Date	09/29/2021
Clinical Overview	Cholestasis is a condition associated with hepatobiliary disorders that cause biliary disruption. One symptom of cholestasis is itching, which can be mild, moderate, or severe in intensity. Two hepatic conditions frequently associated with cholestatic pruritus include Alagille Syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC). ALGS is a rare genetic disorder that causes bile duct abnormalities and bile accumulation in the liver. ALGS occurs in 1 in 30,000 people, and the estimated liver transplant-free survival at 18.5 years of age is 24%. (2,3) Itching occurs in 59% to 88% of patients with ALGS.
Considerations	Priority review • Currently in Phase 3 study for bile acid synthesis disorders
Alternative Therapies	Bylvay (odevixibat) PO

CYLTEZO (ADALIMUMAB), *SC*, BOEHRINGER INGELHEIM

Indication	Interchangeable with Humira for the treatment of certain patients with ankylosing spondylitis, Crohn's disease, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis.
Approval Date	10/15/2021
Clinical Overview	Therapies for the treatment of inflammatory conditions represent one of the highest total cost areas for payers and systems. Currently there are 6 approved biosimilar Humira products: Amgen, BI, Sandoz, Merck/Samsung-Bioepis, Pfizer, and Mylan - all biosimilars have indication extrapolation for 7 of Humira's 10 indications - they lack Humira's pediatric Crohn's disease, hidradenitis suppurativa, and uveitis indications.
Alternative Therapies	Humira (adalimumab) SC

RETHYMIC (ALLOGENIC PROCESSED THYMUS TISSUE-AGDC), *IMPLANT,* ENZYVANT, SUMITOMO DAINIPPON PHARMA, SUMITOVANT

Indication	Immune reconstitution in pediatric patients with congenital athymia.
Approval Date	10/08/2021
Clinical Overview	Congenital athymia is a rare condition in which infants are born without a thymus, resulting in profound immunodeficiency and immune dysregulation. Naïve T cells develop in the thymus, and after leaving the thymus, they fight infection and help regulate the immune system. Without a thymus, children are susceptible to life-threatening infections and immune dysregulation. Pediatric congenital athymia is ultra-rare with an estimated incidence of about 17-24 live births each year in the United States. Children who have this condition are born without a thymus and therefore have profound immunodeficiency, life-threatening immune dysregulation, and high susceptibility to potentially fatal infections. With only supportive care, children with congenital athymia typically die by age 2 or 3.
Considerations	Breakthrough Therapy • Regenerative Advanced Therapy (RMAT) • Rare Pediatric Disease • Orphan Drug Designations
Alternative Therapies	Currently, the only available treatment for these patients outside a clinical trial is supportive care, which may include strict infection prevention measures, including immunoglobulin replacement, prophylactic antimicrobials, and protective isolation.

SUSVIMO (RANIBIZUMAB), *INTRAVITREAL IMPLANT*, GENENTECH, ROCHE

Indication	Wet age-related macular degeneration.
Approval Date	10/22/2021
Clinical Overview	Age-related macular degeneration (AMD) is a common eye condition and a leading cause of vision loss among people 60 years of age and older. There are two types of AMD: dry and wet. Dry AMD is more common, but wet AMD is associated with a more sudden loss of central vision. The loss of central vision in AMD can interfere with simple everyday activities, such as the ability to see faces, drive, read, write, or do close work, such as cooking or fixing things around the house. Approximately 11 million people in the United States have some form of AMD, and of those, about 1.1 million have wet AMD.
Considerations	Priority Review • Healthcare administered
Alternative Therapies	Lucentis (ranibizumab) IVT Byooviz (ranibizumab-nuna) IVT

SCEMBLIX (ASCIMINIB), *ORAL*, NOVARTIS

Indication	Interchangeable with Humira for the treatment of certain patients with ankylosing spondylitis, Crohn's disease, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis.
Approval Date	10/29/2021
Clinical Overview	Chronic myeloid leukemia (CML) is a type of blood cancer that starts in certain cells of the bone marrow. About 15–20% of leukemia cases are CML. It has an annual incidence of 1–2 cases per 100,000. In 2021, there will be an estimated 9,110 new cases of CML in the United States.
Considerations	Orphan drug exclusivity
Alternative Therapies	Tasigna (nilotinib) PO, Sprycel (dasatinib) PO, Bosulif (bosutinib) PO, and Iclusig (ponatinib) PO

BESREMI (ROPEGINTERFERON ALFA-2B-NJFT), *SC*, PHARMAESSENTIA

Indication	Treatment of polycythemia vera in adults.
Approval Date	11/12/2021
Clinical Overview	Polycythemia vera (PV) is a rare blood disease that causes the overproduction of red blood cells. PV can be fatal if not diagnosed and treated, and it can develop into myelofibrosis and malignancies, including acute myeloid leukemia. It is estimated to affect about 44 to 57 per 100,000 people in the United States. Around 6,200 people are diagnosed with PV per year.
Alternative Therapies	hydroxyurea PO, long-acting interferon SC, busulfan PO, and Jakafi (ruxolitinib) PO

VOXZOGO (VOSORITIDE), *SC*, BIOMARIN

Indication	Improve growth in children five years of age and older with achondroplasia and open epiphyses.
Approval Date	11/19/2021
Clinical Overview	Achondroplasia is the most common form of skeletal dysplasia leading to disproportionate short stature. The condition is caused by rare mutations in the fibroblast growth factor receptor 3 (FGFR3) gene. The majority of people with achondroplasia are born to parents of average height. The birth prevalence of achondroplasia in North America ranges from 1:10,000 to 1:30,000. BioMarin estimates there are approximately 3,000 individuals 0–18 years of age with achondroplasia in the United States.
Considerations	Orphan drug exclusivity
Alternative Therapies	Voxzogo is the first FDA-approved treatment for achondroplasia

FYARRO (SIROLIMUS), *IV*, AADI BIOSCIENCE

Indication	Treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) in adults.
Approval Date	11/22/2021
Clinical Overview	Perivascular epitheloid cell tumors (PEComa) are a family of rare tumors of mesenchymal origin included under soft-tissue sarcomas. A subset of PEComa tumors exhibit malignant behavior, with locally invasive recurrences or development of distant metastases most common in the lung. Malignant PEComa is usually not curable. There are an estimated 100-300 patients per year in the United States impacted by this.
Considerations	Orphan drug exclusivity
Alternative Therapies	Rapamune (sirolimus) PO

LIVTENCITY (MARIBAVIR), *ORAL*, SHIRE, TAKEDA

Indication	Post-transplant cytomegalovirus (CMV) infection/disease that does not respond to available antiviral treatment for CMV.
Approval Date	11/23/2021
Clinical Overview	CMV infection is a common type of herpes virus; the CDC estimates that nearly 1 in 3 children in the United States have been exposed to the virus by 5 years of age, and more than half of the U.S. population has been exposed to the virus by 40 years of age. Most people are asymptomatic; however, in immunosuppressed populations, CMV disease can be life-threatening. Of approximately 200,000 adult transplant recipients globally per year, the estimated incidence of CMV infection is 16–56% after solid organ transplant (SOT). In SOT recipients, CMV infection may result in loss of the transplanted organ in up to 25% of cases.
Considerations	Breakthrough therapy • Priority review
Alternative Therapies	Livtencity is the first drug approved to treat refractory CMV. The initial treatment with antiviral drugs include ganciclovir, valganciclovir, foscarnet, or cidofovir.

VYVGART (EFGARTIGIMOD ALFA-FCAB), *IV*, ARGENX

Indication	Treatment of generalized myasthenia gravis in adults who are antiacetylcholine receptor antibody positive.
Approval Date	12/17/2021
Clinical Overview	Myasthenia gravis (MG) is an autoimmune disorder characterized by muscle weakness and fatigue. Patients with MG develop immunoglobulin autoantibodies that attack the acetylcholine receptor, blocking or destroying the receptors, which prevents muscles from contracting. Autoimmune myasthenia gravis has a prevalence of approximately 14-40 per 100,000 individuals in the United States.
Considerations	Fast Track • Orphan Drug Designation
Alternative Therapies	pyridostigmine PO Soliris (eculizumab) IV

TEZSPIRE (TEZEPELUMAB-EKKO), *SC*, AMGEN, ASTRAZENECA, MEDIMMUNE

Indication	Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
Approval Date	12/17/2021
Clinical Overview	The true prevalence of severe asthma is unknown; however, it is estimated that 5–10% of patients with asthma may have severe disease. According to the Global Initiative for Asthma's 2021 report, severe asthma is defined as a subset of difficult-to-treat asthma that is uncontrolled despite adherence to treatment with maximal optimized high-dose inhaled corticosteroids (ICS)/long-acting beta 2-agonists (LABAs) and management of contributory factors, or that worsens when high-dose treatment is decreased.
Considerations	Priority Review • Biologic data exclusivity
Alternative Therapies	Dupixent (dupilumab) SC, Xolair (omalizumab) SC, Nucala (mepolizumab) SC, Fasenra (benralizumab) SC, and Cinqair (reslizumab) IV

YUSIMRY (ADALIMUMAB), *SC*, COHERUS BIOSCIENCES

Indication	Treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.
Approval Date	12/17/2021
Clinical Overview	Therapies for the treatment of inflammatory conditions represent one of the highest total cost areas for payers and systems. Yusimry is the seventh Humira biosimilar to be approved.
Alternative Therapies	Humira (adalimumab) SC

LEQVIO (INCLISIRAN), *SC*, ALNYLAM PHARMACEUTICALS, NOVARTIS

Indication	Heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease as an add-on therapy.
Approval Date	12/22/2021
Clinical Overview	About 38% of American adults have high cholesterol, which increases the risk for developing heart disease and stroke, two leading causes of death in the United States. In 2015-2018, nearly 12% of adults 20 years and older had total cholesterol higher than 240 mg/dL, and about 17% had high-density lipoprotein (HDL, or "good") cholesterol levels less than 40 mg/dL. Slightly more than half of U.S. adults (54.5%, or 47 million) who could benefit from cholesterol medicine are currently taking it.
Alternative Therapies	Praluent (alirocumab) SC, Repatha (evolocumab) SC

ADBRY (TRALOKINUMAB-LDRM), *SC*, ASTRAZENECA, LEO PHARMA, MEDIMMUNE

Indication	Treatment of moderate to severe atopic dermatitis in adults whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; can be used with or without topical corticosteroids.
Approval Date	12/27/2021
Clinical Overview	Atopic dermatitis (AD), a common type of eczema, is a chronic inflammatory skin condition associated with dry skin, intense itching, and thickening of the skin. The scratching and skin damage caused by AD can lead to secondary infections. More than 9.6 million children and about 16.5 million adults in the United States have AD.
Considerations	Orphan drug exclusivity • Biologic data exclusivity
Alternative Therapies	Dupixent (dupilumab) SC

RECORLEV (LEVOKETOCONAZOLE), *ORAL*, STRONGBRIDGE, XERIS

Indication	Treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.
Approval Date	12/30/2021
Clinical Overview	Cushing's disease is the major cause of Cushing's syndrome (excess cortisol in the body) and is caused by a pituitary tumor that oversecretes adrenocorticotropin (ACTH), which leads to overproduction of cortisol by the adrenal glands. Approximately 10 to 15 per million people are affected each year by Cushing's syndrome with an estimated prevalence of 1 per 26,000. Of these, about 70% have Cushing's disease, which can be life threatening if not treated and can cause significant health issues such as obesity, type 2 diabetes, high blood pressure, blood clots, bone loss, immunosuppression, and neuropsychiatric symptoms.
Considerations	Orphan Drug Exclusivity
Alternative Therapies	Isturisa (osilodrostat) PO

KERENDIA (FINERENONE), *ORAL*, BAYER PHARMACEUTICALS

Indication	To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.
Approval Date	07/09/2021
Clinical Overview	Chronic kidney disease (CKD) currently affects 15% of all U.S. adults, or an estimated 37 million people. High blood pressure and diabetes are the main causes of CKD, with approximately 50% of CKD patients also having a diagnosis of diabetes or cardiovascular disease (CVD). The Centers for Disease Control and Prevention (CDC) shows that CKD is more common in people ≥65 years of age, females, and people from minority groups. The estimated prevalence of diagnosed T2D in the U.S. adult population is 8.5% (i.e. 22 million people). Among U.S. adults 18 years of age or older with diabetes, the prevalence of CKD (stages 1–4) is 37%. Therefore, there is a potential population of approximately 8 million people with T2D with CKD in the United States. There is currently no cure for CKD, but treatment can help slow progression.
Considerations	Priority review
Alternative Therapies	Invokana (canagliflozin) PO Farxiga (dapagliflozin) PO

FEXINIDAZOLE, *ORAL*, SANOFI

Indication	Treatment of first-stage (hemolymphatic) and second-stage (meningoencephalitic) human African trypanosomiasis (HAT) due to Trypanosoma brucei gambiense in patients ≥ 6 years of age and weighing ≥ 20 kg.
Approval Date	07/16/2021
Clinical Overview	Human African trypanosomiasis (HAT), also called sleeping sickness, is a rare parasitic disease transmitted by the bite of an infected tsetse fly (found only in rural Africa). Because of effective global programs implemented in the last 20 years, there were less than 1,000 cases reported in 2018. However, experts believe many cases go undiagnosed. Sleeping sickness is almost always fatal if not treated. Existing treatments must be administered via an infusion or injection in a hospital, which can be especially difficult for populations living in remote areas with limited access to adequate health services. It is administered once daily for 10 days. As a result of this approval, Sanofi and DNDi will share equal rights to a tropical disease priority review voucher (PRV). Sanofi will continue to provide the drug free of charge to the World Health Organization (WHO) for distribution to affected countries as part of a long-term collaboration with WHO.
Considerations	Priority review • Orphan designation • Commercial US launch unlikely
Alternative Therapies	Other treatments require intramuscular (IM) or intravenous (IV) administration which can be logistically difficult to access in sub-Saharan Africa where HAT is endemic.

TWYNEO (BENZOYL PEROXIDE/TRETINOIN), *TOPICAL*, SOL-GEL TECHNOLOGIES

Indication	Acne vulgaris in adults and pediatric patients ≥ 9 years of agehospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.
Approval Date	07/26/2021
Clinical Overview	Acne is very common among adolescents and young adults but can persist into adulthood. Nearly 85% of teenagers are affected by acne at some point during their teenage years. In total, over 50 million people have acne in the United States. Permanent scarring, poor self-image, depression, and anxiety can result from acne. Topical therapies are considered first-line.
Considerations	WAC price expected to be similar to other brand-only combination products
Alternative Therapies	benzoyl peroxide topical and tretinoin topical

SEMGLEE (INSULIN GLARGINE), *SC*, VIATRIS (MYLAN)/BIOCON

Indication	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
Approval Date	07/28/2021
Clinical Overview	Sanofi's Lantus (insulin glargine recombinant) is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Two follow-on insulin glargine products are currently on the market: Basaglar single-patient-use prefilled pens (Eli Lilly, Boehringer Ingelheim) and Semglee multiple-dose vials and single-patient-use prefilled pens (Mylan (Viatris), Biocon). In addition to marketing Semglee, Mylan filed an application seeking FDA approval of Semglee as an interchangeable biosimilar version of Lantus. Interchangeable biosimilars may be substituted at the pharmacy for the reference product without the intervention of the prescribing health care provider.
Considerations	First interchangeable exclusivity (12 months)
Alternative Therapies	Lantus (insulin glargine) SC, Toujeo (insulin glargine concentrated) SC, Levemir (insulin detemir) SC, and Basaglar (insulin glargine) SC

QULIPTA (ATOGEPANT), *ORAL*, ABBVIE

Indication	Prevention of episodic migraines in adults.
Approval Date	9/08/2021
Clinical Overview	Migraine is a complex disease with recurrent attacks that are often incapacitating and characterized by severe, throbbing headache pain as well as compounding associated symptoms like nausea or extreme sensitivity to light or sound. In the United States, there are an estimated 37 million people who experience migraine headaches. About 10% of migraineurs meet the diagnostic criteria for chronic migraine, which is characterized by fifteen or more headache days per month, at least eight of which meet the criteria for migraine headache days. The remaining 90% of migraineurs are classified as having episodic migraine. Women are about three times more likely than men to experience migraines.
Alternative Therapies	Nurtec (rimegepant) PO

TAVNEOS (AVACOPAN), *ORAL*, CHEMOCENTRYX

Indication	Adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis in combination with standard therapy including glucocorticoids.
Approval Date	10/07/2021
Clinical Overview	Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AV) is an inflammatory and progressive autoimmune disease affecting the small blood vessels with approximately 75% of patients having renal involvement (rapidly progressing glomerulonephritis). Diagnosis is frequently delayed as symptoms are not specific and multiple organ systems can be affected. When a diagnosis is missed, survival beyond 2 years is unlikely.
Considerations	Orphan Drug Designation
Alternative Therapies	High-dose steroids and immunosuppressants (e.g. cyclophosphamide, rituximab)

TYRVAYA (VARENICLINE), *NASAL*, OYSTER POINT

Indication	Treatment of the signs and symptoms of dry eye disease.
Approval Date	10/15/2021
Clinical Overview	Currently, 30 million people in the United States (14.5% of the U.S. population) report symptoms of dry eye disease (DED), and the prevalence is expected to increase over time as the population ages. Of those reporting symptoms, only an estimated 5 million patients have been diagnosed with DED, and 1 million patients are being treated for DED, leaving a vast untreated population that may seek pharmacological treatment as awareness increases among patients and healthcare practitioners.
Alternative Therapies	Restasis (cyclosporine) single-use and MultiDose • Restasis generics (when launched) • Xiidra (lifitegrast ophthalmic solution) 5% • Cequa (cyclosporine ophthalmic solution) 0.09%

ZIMHI (NALOXONE), *IM/SC*, ADAMIS, US WORLDMEDS

Indication	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
Approval Date	10/15/2021
Alternative Therapies	This is the only injectable naloxone product on the market approved for use by a layperson; nasal formulations include Hikma's Kloxxado (8mg) and Emergent BioSolutions' Narcan (4 mg)

VUITY (PILOCARPINE HYDROCHLORIDE), *OPHTHALMIC*, ABBVIE, ALLERGAN

Indication	Treatment of presbyopia in adults.
Approval Date	10/28/2021
Clinical Overview	Presbyopia is also known as age-related blurry near vision. It is a progressive condition that mainly affects adults 40 years of age and older. In the United States, presbyopia affects around 110 million people.
Considerations	Coverage unlikely since corrective lenses (reading glasses) are commonly available.
Alternative Therapies	Vuity is the first product with this indication.

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Jakafi *ruxolitinib*	Incyte	PO	Graft versus host disease	9/22/2021
Opzelura *ruxolitinib*	Incyte	Topical	Atopic dermatitis	9/21/2021
Tivdak *tisotumab vedotin*	Seattle Genetics; Genmab; Seagen	IV	Cervical cancer	09/20/2021
Cabometyx *cabozantinib s-malate*	Exelixis	PO	Differentiated thyroid cancer	9/17/2021
Byooviz *ranibizumab*	Biogen; Samsung Bioepis	IVT	Wet age-related macular degeneration Macular edema; Myopic choroidal neovascularization	09/17/2021
Brukinsa *zanubrutinib*	BeiGene	PO	Marginal zone lymphoma	09/14/2021
Trudhesa *dihydroergotamine*	Impel NeuroPharma	Nasal	Migraine	09/02/2021
Invega Hafyera *paliperidone palmitate*	Janssen	IM	Schizophrenia	09/01/2021
Brukinsa *zanubrutinib*	BeiGene	PO	Waldenstrom's macroglobulinemia	08/31/2021
Briviact *brivaracetam*	UCB	PO; IV	Partial onset seizures in epilepsy (Monotherapy or adjunctive therapy)	08/27/2021
Loreev XR *lorazepam*	Almatica Pharma	PO	Generalized anxiety disorder	08/27/2021
Vancomycin Injection *vancomycin*	Xellia Pharmaceuticals	PO; IV	Infection	08/26/2021
Tibsovo *ivosidenib*	Servier Agios	PO	Liver cancer	08/25/2021
Xarelto *rivaroxaban*	Bayer; Janssen	PO	Thrombotic cardiovascular events in patients with peripheral arterial disease	08/24/2021
Comirnaty *COVID-19 vaccine, mRNA*	Pfizer; BioNTech	IM	Coronavirus disease 2019 (COVID-19)	08/23/2021
Gvoke *glucagon*	Xeris	SC	Severe hypoglycemia	08/20/2021
succinylcholine	Hikma	IM; IV	General anesthesia	08/20/2021

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Jardiance *empagliflozin*	Eli Lilly; Boehringer Ingelheim	PO	Heart failure	08/18/2021
Lexette *halobetasol propionate*	Mayne	Topical	Plaque psoriasis	08/18/2021
Jemperli *dostarlimab-gxly*	GSK; Tesaro; AnaptysBio	INJ	Solid tumors	08/17/2021
TicoVac *tick-borne encephalitis*	Pfizer	IM	Tick-borne encephalitis	08/13/2021
Xywav *oxybate*	Jazz	PO	Idiopathic hypersomnia	08/12/2021
Mirena *levonorgestrel*	Bayer	Intrauterine	Pregnancy prevention	08/11/2021
Keytruda *pembrolizumab*	Merck & Co	IV	Kidney cancer	08/10/2021
Lenvima *lenvatinib*	Eisai	PO	Kidney cancer	08/10/2021
Micafungin	Teva	IV	Fungal infections	07/30/2021
Nucala *mepolizumab*	GSK	SC	Nasal polyps	07/29/2021
Botox *botulinum toxin type A*	Allergan; AbbVie	IM; ID	Upper limb spasticity	07/28/2021
Keytruda *pembrolizumab*	Merck & Co	IV	Breast cancer	07/26/2021
Drizalma Sprinkle *duloxetine*	Sun	PO	Fibromyalgia	07/23/2021
Bydureon *exenatide*	AstraZeneca	SC	Type 2 diabetes	07/22/2021
Dalvance *dalbavancin*	Allergan; Durata; AbbVie	IV	Acute bacterial skin and skin structure infections	07/22/2021
Keytruda *pembrolizumab*	Merck & Co	IV	Endometrial cancer	07/21/2021
Lenvima *lenvatinib*	Eisai	PO	Endometrial cancer	07/21/2021

ADDITIONAL BRAND APPROVALS

BRAND (GENERIC)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
Prograf *tacrolimus*	Astellas	PO; IV	Prophylaxis of organ rejection	07/16/2021
Vaxneuvance *pneumococcal 15-valent conjugate vaccine*	Merck & Co; Ligand; Pfenex	IM	Pneumococcal disease	07/16/2021
Octagam *immune globulin intravenous (human)*	Octapharma	IV	Dermatomyositis	07/15/2021
Darzalex Faspro *daratumumab; hyaluronidase-fihj*	Janssen; Genmab; Halozyme Therapeutics	SC	Multiple myeloma	07/09/2021
Padcev *enfortumab Vvdotin-ejfv*	Astellas; Seattle Genetics; Agensys; Seagen	IV	Urothelial cancer	07/09/2021
Keytruda *pembrolizumab*	Merck & Co	IV	Squamous cell carcinoma	07/01/2021
TECARTUS *brexucabtagene autoleucel*	Kite Pharma; Gilead	IV	Acute lymphoblastic leukemia	10/01/2021
DEXTENZA *dexamethasone*	Ocular Therapeutics; Ora	PO	Allergic conjunctivitis	10/07/2021
VERZENIO *abemaciclib*	Eli Lilly; Boehringer Ingelheim; Merck & Co	PO	Hormone receptor positive breast cancer	10/12/2021
KEYTRUDA *pembrolizumab*	Merck & Co	IV	Cervical cancer	10/13/2021
SEGLENTIS (CTC) *celecoxib; tramadol*	Esteve	PO	Severe pain	10/15/2021
DUPIXENT *dupilumab*	Genzyme; Regeneron; Sanofi	SC	Asthma	10/20/2021
XIPERE *triamcinolone acetonide*	Bausch + Lomb	INJ	Macular edema	10/25/2021
CUTAQUIG *immune globulin human – hipp*	Octapharma	SC	Pediatric primary immunodeficiency	10/22/2021
Diltiazem	Exela	IV	Atrial fibrillation or atrial flutter; Supraventricular tachycardia including atrial fibrillation	10/28/2021

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
AUDENZ *influenza A H5NI monovalent vaccine adjuvanted*	Seqirus	IM	Influenza subtype A and type B	10/29/2021
PURIFIED CORTROPHIN GEL *corticotropin*	ANI Pharmaceuticals	SC/IM	Chronic autoimmune disorders	11/01/2021
DYANAVEL XR *amphetamine*	Tris Pharma	PO	Attention deficit hyperactivity disorder	11/04/2021
EPRONTIA *topiramate*	Azurity Pharmaceuticals; Eton Pharmaceuticals	PO	Epilepsy	11/05/2021
RUXIENCE *rituximab*	Pfizer	IV	Rheumatoid arthritis	11/15/2021
MVASI *bevacizumab-awwv*	AbbVie; Allergan; Amgen	IV	Epithelial ovarian cancer	11/15/2021
DARZALEX FASPRO *daratumumab; hyaluronidase-fihj*	Genmab; Halozyme Therapeutics; Janssen	SC	Multiple myeloma	11/30/2021
PREHEVBRIO *Hepatitis B Vaccine – Recombinant*	VBI Vaccines	IM	Hepatitis B	11/30/2021
KYPROLIS *carfilzomib*	Amgen; Onyx	IV	Multiple myeloma (refractory, relapsed)	11/30/2021
XACIATO *clindamycin*	Daré Bioscience	Intravaginal	Bacterial vaginosis caused by certain organisms	12/07/2021
ZYNRELEF *bupivacaine; meloxicam*	Heron Therapeutics	PO	Post-operative pain	12/08/2021
ENTADFI *finasteride; tadalafil*	Veru	PO	Symptoms of benign prostatic hyperplasia	12/9/2021
RINVOQ *upadacitinib*	AbbVie	PO	Psoriatic arthritis	12/14/2021
TARPEYO *budesonide*	Calliditas Therapeutics; Pharmalink	PO	IgA nephropathy	12/15/2021
ORENCIA *abatacept*	Bristol-Myers Squibb	IV/SC	Graft versus host disease	12/15/2021

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
DARTISLA ODT *glycopyrrolate*	Edenbridge Pharmaceuticals	PO	Peptic ulcers	12/16/2021
OXBRYTA *voxelotor*	Global Blood Therapeutics	PO	Sickle cell disease in children 4 to 11 years	12/17/2021
CAPLYTA *lumateperone tosylate*	Intra-Cellular Therapies	PO	Schizophrenia and depressive episodes in bipolar I and bipolar II disorder	12/17/2021
REZVOGLAR *insulin glargine-aglr*	Eli Lilly	SC	Diabetes mellitus	12/17/2021
OTEZLA *apremilast*	Amgen; Celgene	PO	Mild to moderate plaque psoriasis	12/20/2021
XARLETO *rivaroxaban*	Bayer; Janssen	PO	Prophylaxis and treatment of venous thromboembolism	12/20/2021
COSENTYX SC *secukinumab*	Novartis	SC	Juvenile psoriatic arthritis and active enthesitis-related arthritis	12/22/2021

PRODUCTS IN THE PIPELINE

PIPELINE NAME (GENERIC)	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
oteseconazole	Viamet; Mycovia Pharmaceuticals	PO	Vulvovaginal candidiasis	Pending (01/27/2022)
vonicog alfa	Shire; Baxalta	IV	Von Willebrand disease	Pending (01/28/2022)
aminolevulinic acid	Biofrontera	Topical	Actinic keratosis	Pending (01/2022)
daridorexant	Idorsia	PO	Insomnia	Pending (01/2022)
carbetocin	Ferring Pharmaceuticals; Levo Therapeutics	Nasal	Prader-Willi syndrome	Pending (01/2022)
somatrogon	Pfizer; OPKO Health	SC	Pediatric growth hormone deficiency	Pending (01/2022)
faricimab	Roche	IVT	Wet age-related macular degeneration Diabetic macular edema	Pending (01/2022)
sutimlimab	Sanofi; Bioverativ	IV	Cold agglutinin disease	Pending (02/05/2022)
mitapivat	Agios	PO	Pyruvate kinase deficiency	Pending (02/17/2022)
tebentafusp	Immunocore	IV	Uveal melanoma	Pending (02/23/2022)
bardoxolone	Reata	PO	Alport syndrome	Pending (02/25/2022)
Filsuvez	Amryt Pharma	Topical	Epidermolysis bullosa	Pending (02/28/2022)
ciltacabtagene autoleucel	Janssen Legend; Biotech	IV	Multiple myeloma	Pending (02/28/2022)
pacritinib	CTI; BioPharma	PO	Myelofibrosis	Pending (02/28/2022)
immune globulin intravenous (human)	Green Cross; GC Pharma	IV	Primary immunodeficiency	Pending (02/2022)
risankizumab-rzaa	Boehringer Ingelheim; AbbVie	SC	Psoriatic arthritis	Pending (02/2022)
setmelanotide	Rhythm Pharmaceuticals	SC	Obesity	Pending (03/16/2022)
nivolumab; relatlimab	Bristol-Myers Squibb	IV	Melanoma	Pending (03/19/2022)
ganaxolone	Marinus	PO; INJ	CDKL5 deficiency disorder	Pending (03/20/2022)
gefapixant	Merck & Co	PO	Refractory chronic cough	Pending (03/21/2022)
fenfluramine	Zogenix	PO	Lennox-Gastaut syndrome	Pending (03/25/2022)
ublituximab	TG Therapeutics	IV	Chronic lymphocytic leukemia	Pending (03/25/2022)
udenafil	Allergan AbbVie; Mezzion	PO	Fontan palliation	Pending (03/26/2022)

PRODUCTS IN THE PIPELINE

PIPELINE NAME (GENERIC)	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
luspatercept-aamt	Bristol-Myers; Squibb; Celgene; Acceleron	SC	Non-transfusion-dependent thalassemia	Pending (03/27/2022)
pembrolizumab	Merck & Co	IV	Endometrial cancer	Pending (03/28/2022)
vadadustat	Otsuka; Fresenius; Akebia; Therapeutics; Vifor	PO	Anemia due to kidney disease	Pending (03/29/2022)
letibotulinumtoxina	Hugel; Croma-Pharma GmbH	INJ	Glabellar frown lines	Pending (03/31/2022)
estradiol; progesterone	TherapeuticsMD	PO	Vasomotor symptoms due to menopause (hot flashes)	Pending (03/2022)
sintilimab	Eli Lilly Innovent Biologics (Suzhou)	IV	Non-small cell lung cancer	Pending (03/2022)
tecovirimat	SIGA Technologies	IV	Smallpox	Pending (03/2022)
dapivirine	Janssen	Intravaginal	Prophylaxis to reduce risk of sexually acquired HIV-1	Pending (1Q 2022)
benralizumab	AstraZeneca; MedImmune; Kyowa; Kirin	SC	Nasal polyps	Pending (1Q 2022)