AscellaHealth®

Specialty and Rare Pipeline Digest™

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WELCOME TO ASCELLAHEALTH'S SPECIALTY AND RARE PIPELINE DIGEST™

As the pipeline of new specialty pharmaceuticals continues to evolve, it becomes even more crucial to stay abreast of recent and emerging therapeutic options on the horizon. Our quarterly publication provides all industry stakeholders with important insights into specialty, rare disease and cell and gene therapy pipelines, recent approvals, and upcoming FDA reviews.

TABLE OF CONTENTS

About AscellaHealth

WHO WE ARE

AscellaHealth is a mission-driven, global healthcare company focused on solving challenges across the complex specialty and retail pharmaceutical ecosystem—always with patients at the center of what we do. We partner with payers, pharmaceutical manufacturers, and healthcare stakeholders to improve access to critical therapies through technology-enabled solutions that span the full pharmaceutical lifecycle, from commercialization and specialty pharmacy to care coordination, distribution, and pharmacy management. Supporting more than 450 health partners and 1.2 million patients worldwide, our work makes a meaningful difference every day.

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WHAT WE DO

AscellaHealth's global end-to-end solutions for life sciences manufacturers, payers and other stakeholders span the entire product lifecycle and are instrumental in the launch of specialty and rare disease medications, and include:

- Pre-Commercialization & Market Access
- International Specialty Pharmacy Fulfillment
- Exclusive Distribution Partnerships & Supply Chain Logistics
- Patient Support & HUB Services
- Infusion Site of Care & SP Fulfillment Programs
- Medication Access Programs
- Specialty Pharmacy & Medical Benefit Management
- Customized Clinical Programs

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Dupixent (dupilumab)	Sanofi; Genzyme; Regeneron	Subcutaneous	Interleukin 4 receptor (IL-4R) antagonist	Allergic fungal rhinosinusitis	Approved (02/24/2026)	$55,000	Low

On February 24, 2026, Dupixent® was approved for the treatment of adults and children aged 6 years and older with allergic fungal rhinosinusitis (AFRS). This approval makes it the ninth FDA-approved indication for Dupixent, and it is the first and only drug therapy indicated specifically for AFRS.

AFRS is a chronic type 2 inflammatory disorder of the sinuses driven by an exaggerated allergic immune response to fungi. It may cause nasal polyps, persistent nasal blockage, reduced or lost sense of smell, thick mucus drainage, diminished health-related quality of life, bone erosion around the sinuses, and facial deformities. AFRS is a distinct subtype of chronic rhinosinusitis with nasal polyps and can be particularly challenging to manage due to its limited responsiveness to currently available therapies. The standard treatment approach involves sinus surgery combined with extended courses of systemic corticosteroids, though recurrence of the disease remains common.

The study evaluating the safety and efficacy of Dupixent for AFRS met the primary endpoint demonstrating a change from baseline to week 52 in sinus opacification scores. Sinus opacification scores (a measure of nasal congestion as assessed by computed tomography [CT] scans) improved by 50% in the Dupixent group versus 9.8% in the placebo group at week 52. A significant reduction in sinus opacification scores was also observed at 24 weeks. Additionally, Dupixent demonstrated significant reductions in key disease signs and symptoms including nasal congestion, and nasal polyps compared to placebo. Furthermore, patients in the Dupixent group had a 92% lower risk of systemic corticosteroid use and/or need of surgery compared to those in the placebo group at week 52.

Dupixent will likely be reserved for use in patients who have failed nasal corticosteroids and who have had failure/recurrence after sinus surgery or systemic corticosteroid use. Dupixent is also approved for atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic obstructive pulmonary disease and bullous pemphigoid.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Zycubo (copper histidinate)	Zydus; Sentynl Therapeutics	Subcutaneous	Copper supplement	Menkes disease	Approved (01/12/2026)	Patients <1 year of age: $1.3 million Patients 1 to 17 years of age: $680,000	Low

On January 12, 2026, the FDA approved Zycubo® for the treatment of Menkes disease (MD) in pediatric patients. MD is a rare X-linked recessive disorder of copper metabolism caused by mutations in the ATP7A gene. The condition is marked by seizures, poor growth and weight gain, developmental delays, and intellectual disability. It also causes abnormalities affecting the blood vessels, bladder, intestines, bones, muscles, and nervous system. Approximately 90% of affected individuals have the classic form, with symptoms emerging in infancy; most children with this form do not survive beyond three years of age. The disease occurs in an estimated 1 in 100,000 to 250,000 live births worldwide and is seen more frequently in boys. Without treatment, most affected individuals do not survive beyond 3 years of age.

Zycubo is the first treatment FDA-approved for MD and is a bioavailable copper replacement therapy that is administered subcutaneously (SC). It delivers copper in a form that bypasses the genetic defect in intestinal absorption, allowing the body to better use the mineral.

The efficacy of Zycubo was evaluated in pediatric patients with MD receiving 3 years of copper histidinate treatment in two trials. Overall survival was assessed by comparing treated patients to untreated patients from contemporaneous external control groups. The analysis included 66 treated patients and 17 untreated patients, most of whom were from the United States.

Children who began treatment within four weeks of birth had a 78% reduction in the risk of death compared with untreated patients. Nearly half of early-treated patients survived beyond six years, and some survived more than 12 years. No patients in the untreated control group survived beyond six years. Children who started treatment later than four weeks after birth also experienced a substantial survival benefit.

Historically, treatment options for MD have been extremely limited and largely supportive. Supportive care measures include seizure management, nutritional support (including gastrostomy tube placement), physical and occupational therapy, management of recurrent infections, and autonomic instability. Copper supplementation using non-standardized compounded injectable copper histidinate has been used off-label for decades. However, response varies because copper must cross both the gastrointestinal (GI) tract and the blood brain barrier (BBB), and treatment effectiveness depends on whether the underlying ATP7A mutation allows residual copper transport.

The variation in Zycubo's price across age groups is primarily driven by differences in dosing requirements. Patients younger than one year require twice-daily dosing, whereas patients aged one year and older receive the medication once daily, resulting in lower overall drug utilization in the older age group.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Cablivi (caplacizumab)	Sanofi; Ablynx	Intravenous; Subcutaneous	Von Willebrand factor	Thrombotic thrombocytopenic purpura	Approved (12/23/2025)	$312,000	Low

The FDA expanded the approval of Cablivi® to include treatment of pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenia purpura (Attp), in combination with plasma exchange and immunosuppressive therapy. Previously the treatment had only been approved for adults.

Thrombotic thrombocytopenic purpura (TTP) is a rare blood disorder marked by a profound decrease in platelets (thrombocytopenia), destruction of red blood cells (hemolytic anemia), and the formation of small clots in the body's smallest blood vessels. These microvascular clots can disrupt blood flow and lead to complications affecting the brain and other organs.

While the precise cause of TTP is not always clear, it is commonly associated with a deficiency of the enzyme ADAMTS13, which normally cleaves the clotting protein von Willebrand factor. When ADAMTS13 activity is severely reduced, unusually large von Willebrand factor multimers accumulate, promoting abnormal clot formation. TTP may be inherited—referred to as congenital TTP (cTTP)—or acquired due to immune-mediated inhibition of ADAMTS13, known as immune-mediated or acquired TTP (aTTP or iTTP).

Caplacizumab is an antibody fragment that targets von Willebrand factor (vWF) and blocks its interaction with platelets, thereby reducing vWF-mediated platelet adhesion and platelet consumption. The expanded approval was supported by findings from an observational, retrospective chart review study that enrolled 30 pediatric patients aged 2 to 18 years with acquired thrombotic thrombocytopenic purpura (aTTP), including 21 patients older than 12 years and 9 patients aged 12 years or younger. Of the 30 patients, 29 underwent plasma exchange after initiating caplacizumab, with a median treatment duration of six days. Most participants (90%) received the standard adult dose at treatment initiation.

Overall, 80% of patients achieved clinical remission, defined as a platelet count of at least 150 × 10⁹/L and a lactate dehydrogenase (LDH) level below 1.5 times the upper limit of normal (ULN) for at least 30 days following discontinuation of therapeutic plasma exchange (TPE). The median time to platelet response—measured from the start of caplacizumab to the first platelet count ≥150 × 10⁹/L, followed by discontinuation of daily TPE within five days—was five days. Refractory aTTP, defined as failure of the platelet count to double after four days of caplacizumab treatment with persistent LDH above the ULN, was observed in 6.7% of patients. Relapse (recurrence more than 30 days after the last TPE) occurred in 6.7% of participants, and no cases of aTTP exacerbation (recurrence within 30 days of the last TPE) were reported.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Aqvesme (mitapivat)	Agios	Oral	Pyruvate kinase activator	Beta-thalassemia; Alpha-thalassemia; Non-transfusion-dependent thalassemia (NTDT)	Approved (12/23/2025)	$425,000	Low

On December 23, 2025, the FDA approved Aqvesme™ (mitapivat) for the treatment of anemia in adults with alpha or beta thalassemia. Aqvesme is a pyruvate kinase activator administered twice daily as an oral tablet.

Thalassemia is a group of rare blood disorders affecting the hemoglobin genes and resulting in ineffective erythropoiesis, which can lead to fewer red blood cells (RBCs) and severe anemia. There are two main forms of thalassemia: alpha thalassemia and beta thalassemia. Alpha thalassemia is caused by reduced or absent production of alpha-globin subunits, while beta thalassemia is caused by reduced or absent production of beta-globin subunits.

Aqvesme is the first FDA-approved treatment for alpha thalassemia and non–transfusion-dependent beta thalassemia and the only oral treatment to be approved for transfusion-dependent beta thalassemia. For transfusion-dependent beta thalassemia, Aqvesme may compete with Bristol Myers Squibb's Reblozyl® (luspatercept-aamt), an erythroid maturation agent administered subcutaneously every 3 weeks. Potentially curative one-time treatments for transfusion-dependent beta thalassemia include Casgevy® (exagamglogene autotemcel) and Zynteglo™ (betibeglogene autotemcel), as well as hematopoietic stem cell transplant. Prior to Aqvesme's approval, limited treatment options were available for alpha thalassemia and hydroxyurea could be used off-label for non–transfusion-dependent beta thalassemia.

Mitapivat was initially approved in February 2022 under the brand name Pyrukynd for the treatment of hemolytic anemia in adults with pyruvate kinase deficiency (PKD) and it continues to be marketed for that indication without a REMS requirement. The company later introduced Aqvesma as a separate brand, likely due in part to REMS considerations, allowing for differentiated pricing. Aqvesma's annual cost is $425,000, compared with $335,800 for Pyrukynd.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Wegovy (tablet) (semaglutide)	Novo Nordisk	Oral	Glucagon-like peptide-1 (GLP-1) agonist	Obesity*; Reduce cardiovascular mortality in patients with obesity*	Approved (12/22/2025)	$16,400	High

On December 22, 2025, the FDA approved Novo Nordisk's Wegovy® (semaglutide) tablets for two indications in combination with a reduced calorie diet and increased physical activity: 1) to reduce excess body weight and maintain weight reduction long term in adults with obesity, or overweight adults in the presence of at least one weight-related comorbid condition and 2) to reduce the risk of major adverse cardiovascular (CV) events (MACE; CV death, nonfatal myocardial infarction, or nonfatal stroke) in adults with established CV disease and either obesity or overweight. Wegovy tablet is the first oral glucagon-like peptide-1 (GLP-1) receptor agonist FDA-approved for weight management and the second oral GLP-1 to market overall, following Rybelsus (semaglutide) that was approved in 2019 for type 2 diabetes.

Approval of Wegovy tablets for weight management was supported by findings from the OASIS 4 trial, which enrolled 307 adults with obesity or overweight and at least one weight-related comorbidity. At 64 weeks, participants treated with Wegovy 25 mg achieved an average weight loss of 13.6%. In a comparative study evaluating a higher dose of Wegovy subcutaneous against the standard 2.4 mg subcutaneous dose, patients receiving the higher dose achieved a mean weight reduction of 18.7% at 72 weeks, compared with 15.6% in the 2.4 mg group. While not a head-to-head trial, the oral form may not produce as great of a weight loss as compared to the subcutaneous version at usual doses.

The indication for reduction of major adverse cardiovascular events (MACE) was based exclusively on data from the SELECT and STEP clinical trial programs evaluating injectable Wegovy, along with the PIONEER PLUS trial of Rybelsus®. No dedicated cardiovascular outcomes study was conducted specifically for the Wegovy tablet formulation.

The most notable near-term competitor to Wegovy tablets is expected to be orforglipron. In the pivotal ATTAIN-1 trial, patients receiving the highest dose of orforglipron (36 mg) experienced an average weight loss of 11.2% at Week 72. By comparison, in the OASIS 4 study, patients treated with the highest dose of the Wegovy tablet formulation (25 mg) achieved a mean weight reduction of 13.6% at Week 64. Since orforglipron is a nonpeptide GLP-1 receptor agonist, if approved, it is not anticipated to carry the same administration restrictions as Wegovy tablets, which must be taken in the morning on an empty stomach with water and require patients to avoid other food, beverages, or medications for at least 30 minutes. Discontinuation rates due to adverse events were similar for both treatments, at approximately 6% across dose levels.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Myqorzo (aficamten)	Cytokinetics	Oral	Cardiac muscle myosin inhibitor	Hypertrophic cardiomyopathy	Approved (12/19/2025)	$108,400	Low

On December 19, 2025, the FDA approved Myqorzo™ for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. Hypertrophic cardiomyopathy is a disease characterized by the abnormal thickening of the cardiac muscle, which results in symptoms such as chest pain, dizziness, shortness of breath or fainting during physical activity. Myqorzo is designed to reduce heart muscle contraction by binding directly to cardiac myosin, a protein that regulates heart contractions.

Approval was based on a trial which included 282 participants who received either Myqorzo or placebo for 24 weeks. The study demonstrated that Myqorzo significantly increased peak oxygen uptake (pVO2) by 1.8 mL/kg/min versus 0.0 mL/kg/min with placebo. Myqorzo was well tolerated, with no instances of worsening heart failure or treatment interruption due to low ventricular ejection fraction. However, the label for Myqorzo includes a Boxed Warning for heart failure risk due to systolic dysfunction and Myqorzo is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

Myqorzo will compete against Camzyos®, which is another oral cardiac myosin inhibitor for obstructive hypertrophic cardiomyopathy approved in 2022 and with a comparable price tag of about $106,000 per year. Both medications carry a boxed warning for the risk of heart failure due to systolic dysfunction; however, Myqorzo holds an advantage over Camzyos in how declines in LVEF are managed once therapy is underway. Dosing of Myqorzo may be decreased — rather than interrupted — if a patient's LVEF is <50% and ≥40%, or in the case of HF symptoms or worsening clinical status resulting from systolic dysfunction. By contrast, Camzyos must be discontinued if LVEF drops <50%.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Jascayd (nerandomilast)	Boehringer Ingelheim	Oral	Phosphodiesterase-4 (PDE4) Inhibitor	Interstitial lung disease	Approved (12/19/2025)	$197,000	Low

On December 19, 2025, the FDA approved Jascayd® (nerandomilast), an oral preferential inhibitor of phosphodietsterase-4B (PDE4B), for the additional indication of treatment of progressive pulmonary fibrosis (PPF) in adult patients. Jascayd was previously approved in October 2025 for the treatment of idiopathic pulmonary fibrosis (IPF) and it may be used as monotherapy or in combination with Ofev® or Esbriet® for this indication. Progressive pulmonary fibrosis (PPF) refers to a form of interstitial lung disease (ILD) in which lung scarring (fibrosis) continues to worsen over time despite appropriate management and regardless of the underlying cause. PPF is not a single disease, but a clinical phenotype seen in various fibrotic ILDs—including autoimmune-related ILD, chronic hypersensitivity pneumonitis, sarcoidosis-associated fibrosis, and others—when they demonstrate ongoing progression.

The approval was based on data from a trial which included 1,178 adults with PPF with or without background treatment with Ofev (nintedanib). Participants were randomly assigned 1:1 to receive nerandomilast 9mg, nerandomilast 18mg, or placebo twice daily until the last patient received treatment for 52 weeks. The primary objective was to determine whether nerandomilast could slow the rate of lung function decline compared with placebo. Lung function was assessed using forced vital capacity (FVC), a standard measure of how much air a patient can forcibly exhale.

Results demonstrated that treatment with nerandomilast significantly reduced the rate of FVC decline compared with placebo, indicating a slowing of disease progression. Overall, the findings suggest that nerandomilast may represent a potential new therapeutic option for patients with progressive pulmonary fibrosis by helping to preserve lung function and slow disease progression.

Jascayd may be used as an add-on treatment to Ofev which was approved in 2020 for the treatment of adults with CF-ILD with a progressive phenotype and is recommended in guidelines for the treatment of PPF in patients who have failed standard management (e.g., immunosuppressive agents (mycophenolate mofetil, azathioprine), Ofev) for fibrotic ILD It could also be used as monotherapy in both treatment-naïve patients and those previously treated with Ofev.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Exdensur (depemokimab)	GSK	Subcutaneous	Interleukin 5 (IL-5) antagonist	Eosinophilic asthma*	Approved (12/16/2025)	$52,000	Moderate

On December 16, 2025, the FDA approved Exdensur (depemokimab-ulaa), an interleukin-5 (IL-5) antagonist, as an add-on maintenance treatment for severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients 12 years of age and older. It is the first long-acting biologic approved for twice-yearly dosing in asthma with an eosinophilic subtype.

Asthma is a common disease characterized by chronic airway inflammation, which include respiratory symptoms such as wheezing, shortness of breath, chest tightness, and cough. Eosinophilic asthma is a subtype of asthma characterized by elevated levels of eosinophils, a type of white blood cell involved in inflammation. These cells accumulate in the airways and contribute to swelling, mucus production, and airway narrowing, leading to breathing difficulties.

Exdensur was evaluated in 2 trials in which patients received either Exdensur 100mg or placebo subcutaneously once every 6 months. The primary endpoint was the annualized rate of clinically significant exacerbations defined as worsening of asthma requiring use of systemic corticosteroids for at least 3 days or a single intramuscular corticosteroid dose and/or hospitalization and/or emergency department (ED) visit, over the 52-week treatment period.

Results showed that treatment is Exdensur resulted in a 58% reduction in the rate of annualized asthma exacerbations compared with placebo in one trial. The second trial showed that patients in the Exdensur group had a 48% reduction in the rate of annualized asthma exacerbations vs placebo. Fewer patients treated with Exdensur had exacerbations requiring hospitalization and/or ED visits compared with those who received placebo. The time to first clinically significant exacerbation was longer with Exdensur than with placebo in both trials. Additionally, lung function was also measured by pre-bronchodilator FEV1, over 52 weeks. In the first trial, the mean improvement from baseline in FEV1 with Exdensur was 160ml, compared with 160ml for placebo, resulting in no difference between treatment and placebo. IN the second trial, the mean increase in FEV1 with Exdensur was 240mg versus 184ml with placebo, giving a treatment difference of 56ml.

Exdensur will compete with currently approved biologics for severe asthma; Tezspire® (tezepelumab), Nucala (mepolizumab), and Cinqair® (reslizumab) are dosed every 4 weeks. Xolair® (omalizumab) can be administered every 2 or 4 weeks, Dupixent® (dupilumab) is given every 2 weeks, and Fasenra® (benralizumab) is administered every 8 weeks. None of these products currently face biosimilar competition; however, Xolair biosimilars are anticipated to launch in the second half of 2026, and Nucala may potentially lose exclusivity in 2027+.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Cardamyst (etripamil)	Milestone Pharmaceuticals	Nasal	L-type calcium channel blocker	Supraventricular tachycardia*	Approved (12/12/2025)	$1,700/2 doses	Low

On December 12, 2025, the FDA approved Cardamyst™, a calcium channel blocker nasal spray, for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. It is designed for rapid intranasal self-administration outside of emergency and/or healthcare settings.

Paroxysmal supraventricular tachycardia is a clinical syndrome characterized by the presence of regular and rapid tachycardia of abrupt onset and termination, often leading to emergency department visits. Symptoms include shortness of breath, chest pain, and dizziness. It is the second most common tachyarrhythmia following atrial fibrillation (AFib). PSVT affects more than 2 million U.S. adults.

Cardamyst is an intranasal, self-administered, non-dihydropyridine calcium channel blocker designed to be absorbed in to the bloodstream in <10 minutes for the conversion of acute symptomatic episodes of PSVT to sinus rhythm in adults.

Approval was based on results from several phase 3 trials. In one trial, 64% of patients who self-administered Cardamyst converted from supraventricular tachycardia to sinus rhythm within 30 minutes, versus 31% on placebo. At 1 hour, the rate was 73%.

Cardamyst is the first and only self-administered treatment offering patients an FDA-approved option to manage episodes of PSVT outside the emergency or healthcare setting. Currently, when conservative measures fail to resolve an acute episode of PSVT, the standard of care in the outpatient setting is the off-label use of low-cost, generic, oral medications (e.g., diltiazem, verapamil, or beta blockers).

Cardamyst will be supplied as two disposable nasal spray devices and each device delivers two sprays for a total dose of 70mg per device. The recommended administration is two sprays at the onset of symptoms, with an additional dose if symptoms persist. The maximum allowable dose is 140 mg within a 24-hour period. Based on clinical trial data, up to four cartons may be needed per calendar year.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Lerochol (lerodalcibep)	LIB Therapeutics	Subcutaneous	PCSK9 inhibitor	Hypercholesterolemia; Heterozygous familial hypercholesterolemia (HeFH)	Approved (12/12/2025)	Not yet available	Low

On December 12, 2025, the FDA approved Lerochol™ (lerodalcibep-liga), a PCSK9 inhibitor, as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Dyslipidemia is defined as an imbalance of lipids such as cholesterol, LDL-C, triglycerides (TGs), and high-density lipoprotein cholesterol (HDL-C). Hypercholesterolemia (HC) is the most common form of dyslipidemia and is associated with elevated LDL-C levels.

The approval was supported by data from 3 randomized, double-blind, placebo-controlled trials that enrolled 2,017 adults with HeFH, clinical atherosclerotic cardiovascular disease (ASCVD), or increased risk of ASCVD, who were on a stable low-fat, low-cholesterol diet and maximally tolerated statin therapy and who required additional LDL-C lowering. In the three clinical trials, Lerochol demonstrated mean LDL-C reductions of 50%–55% in patients with, or at very high or high risk of CVD, and ≥59% in those with HeFH who have more severe LDL elevations.

Lerochol is launching into a very competitive hyperlipidemia treatment landscape, including three other available PCSK9 inhibitors; Repatha®, Praluent® and Leqvio®. Without direct head-to-head comparison with the other available agents and a lack of cardiovascular outcomes data, Lerochol will rely upon its once-monthly administration as a potential advantage to the more established, clinically proven, self-administered products (Repatha and Praluent).

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Annual Cost	Impact
Uplizna (inebilizumab)	AstraZeneca; Amgen; MedImmune; Horizon Therapeutics; Viela Bio	Intravenous	Anti-CD19 antibody	Myasthenia gravis	Approved (12/11/2025)	$280,497	Low

On August 29, 2025, the FDA approved Uplizna®, a CD19 targeted B-cell therapy for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+). gMG is a rare, unpredictable, chronic, B-cell-mediated autoimmune disorder that impairs neuromuscular communication and can cause fluctuating muscle weakness. The disease is thought to be primarily driven by AChR and MuSK autoantibodies, which are produced by CD19+ B cells. Myasthenia gravis impacts 80,000 to 100,000 people in the U.S.

The approval for gMG was supported by data from a study which evaluated inebilizumab, a CD-19 directed cytolytic antibody, in 238 patients with gMG, including 190 patients who were anti-AChR-Ab+ and 48 patients who were anti-MuSK-Ab+. The primary efficacy measure was the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, which measures gMG symptoms, scoring ranges from 0 to 24, with higher scores indicating greater disease activity. Findings showed in the overall population, treatment with inebilizumab demonstrated a statistically significant improvement in MG-ADL total score compared with placebo -4.2 vs -2.2 points difference, respectively. In the anti-AChR-Ab+ population, inebilizumab resulted in a 4.2 point decrease in the MG-ADL total score compared with a 2.4 point reduction with placebo, and the anti-MuSK-Ab+ population showed a reduction of 3.9 and 1.7 points, respectively.

In the overall population, a statistically significant difference favoring inebilizumab over placebo was observed for the key secondary endpoint of mean change from baseline in QMG total score -4.8 vs -2.3 points. Patients who were anti-AChR-Ab+ saw a statistically significant difference in QMG score vs placebo; however, those who were anti-MuSK-Ab+ did not.

This is the third indication for Uplizna, which was previously approved by the FDA for the treatment of adult patients with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) in June 2020, and for the treatment of adult patients with Immunoglobulin G4-related disease (IgG4-RD) in April 2025.

Uplizna is the first gMG treatment that can be administered every 6 months. It will compete with Imaavy™ (nipocalimab-aahu) and Rystiggo® (rozanolixizumab-noli) for patients who are anti–MuSK Ab+ and with all other approved gMG treatment options for patients who are anti–AChR Ab+, which includes Imaavy and Rystiggo , Vyvgart® (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Soliris® (eculizumab), Ultomiris® (ravulizumab) and Zilbrysq® (zilucoplan).

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Dupixent (dupilumab)	Sanofi; Genzyme; Regeneron	Subcutaneous	Interleukin 4 receptor (IL-4R) antagonist	Chronic idiopathic urticaria (CIU)	Pending (4/27/2026	sBLA

Dupixent® is being evaluated for the treatment of chronic idiopathic urticaria (CIU) in patients 2 to 11 years of age with the same trial design as that performed for patients 12 years of age and older. In April 2025, the FDA approved Dupixent for the treatment of adult and pediatric patients 12 years of age an older with chronic spontaneous urticaria who remain symptomatic despite antihistamine treatment. The approval was based on the results from two phase 3 clinical studies, study A and LIBERTY-CUPID study C.

Chronic spontaneous urticaria is a condition characterized by the development of hives, angioedema, or both. It can be either acute, lasting 6 weeks or less, or chronic, greater than 6 weeks in duration. Chronic urticaria (CU) is classified into two main subtypes: chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU). CSU is defined by the presence of recurrent, itchy wheals (hives), angioedema, or both, persisting for six weeks or longer without a clear external trigger. It was previously referred to as chronic idiopathic urticaria (CIU). In contrast, CIndU presents with similar symptoms, but episodes are triggered by specific, identifiable stimuli—either physical or nonphysical—such as cold, heat, pressure, cholinergic stimuli, sunlight, or water exposure. CSU represents approximately 70% to 80% of all CU cases, although some individuals experience features of both subtypes.

The phase 3 study enrolled a total of 151 children and adults with CSU. Patients were randomized to receive either dupilumab (n=74) or a placebo (n=77) in addition to an H1 antihistamine. By week 24, investigators reported that 30% of patients treated with dupilumab achieved complete response, versus 18% of patients receiving the placebo.

They also reported a more significant reduction in itch achieved with dupilumab (8.64-point reduction) when compared with placebo (6.1-point reduction). Patients treated with dupilumab also experienced a more significant reduction in urticaria activity severity, measuring itch and hive symptoms, from baseline to week 24 (15.86-point reduction) versus placebo (11.21-point reduction).

These findings confirm data from the LIBERTY-CUPID Study A, in which dupilumab demonstrated nearly doubled reductions in measures of itch and urticaria versus standard of care alone. The estimated cost will be similar to the cost for other treatments ranging from $50,000 to $55,000 for therapy.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Sotyktu (tablet) (Deucravacitinib)	Bristol-Myers Squibb	Oral	Tyrosine kinase 2 (TYK2) inhibitor	Psoriatic arthritis	Pending (03/06/2026)	sNDA

Deucravacitinib is an oral tyrosine kinase 2 (TYK2) inhibitor being investigated for the treatment of psoriatic arthritis in adults.

Psoriatic arthritis (PsA) is a chronic, autoimmune disease that involves the joints and can often occur in people who also have psoriasis, an autoimmune skin condition that results in scaly, red itchy patches. The annual incidence of PsA in patients with psoriasis is 2.7%, and the reported prevalence of PsA among patients with psoriasis has varied between 6% and 41%. In the majority of patients, the skin symptoms develop first, followed by the arthritis; however, in some patients the skin and joint symptoms present at the same time, and in 10–15% the arthritis presents first.

One trial evaluating treatment with Sotyktu compared to placebo showed that the primary endpoint of ACR20 was achieved in 54.2% of patients compared to 34.1% of those in the placebo group. The second trial had similar results with ACR20 achieved by 54.2% of patients in the Sotyktu group and 39.4% in the placebo group.

Sotyktu was approved in September 2022 for plaque psoriasis and is also in development for other inflammatory conditions. It will compete mainly with Amgen's Otezla and oral JAK inhibitors such as Rinvoq. The cost is estimated to be similar to that for psoriasis at around $85,000 per year.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
GSK2330672 (linerixibat)	GSK	Oral	Ileal bile acid transporter (IBAT) inhibitor	Pruritus in primary biliary cholangitis	Pending (03/24/2026)	NDA

Linerixibat is a targeted oral ideal bile acid transporter (IBAT) inhibitor. IBAT is responsible for the reabsorption of bile acids from the terminal ileum back into the liver via the portal vein. By blocking this transporter, linerixibat reduces the reabsorption of bile acids, leading to increased excretion of bile acids through the feces. This reduction in bile acid levels in the liver and bloodstream may help to alleviate the symptoms associated with bile acid buildup, including pruritus.

Primary biliary cholangitis (PBC) is a chronic autoimmune liver disease characterized by the progressive destruction of the bile ducts within the liver. This leads to the accumulation of bile, causing inflammation and scarring, which can eventually result in liver cirrhosis and liver failure. It primarily affects women aged 40 to 60 and often presents with fatigue, severe itching, dry eyes/mouth, or jaundice.

The safety and efficacy of linerixibat was evaluated in a study in which patients were randomly assigned to receive either linerixibat or placebo. Results showed that patients in the linerixibat group met the primary endpoint, showing a significant improvement in itch over 24 weeks compared with placebo. The trial also met key secondary endpoints, including itch score at week 2 and itch-related sleep interference as measured on a 1-10 numerical rating scale (NRS) over 24 weeks. The most common adverse event was diarrhea, which occurred in 61% of patients on linerixibat versus 18% of people on placebo and led to discontinuation in 4% of patients on linerixibat versus <1% of people on placebo.

Linerixibat would compete as second-line therapy with Iqirvo and Livdelzi, which are currently available, as well as volixibat which is another bile acid transporter (IBAT) therapy currently being investigated. The estimated price is between $100,000 - $300,000 per year.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Wegovy (injection) (7.2 mg) (semaglutide)	Novo Nordisk	Subcutaneous	Glucagon-like peptide-1 (GLP-1) agonist	Obesity	Pending (1Q 2026)	sNDA
CagriSema (cagrilintide; semaglutide)	Novo Nordisk	Subcutaneous	Glucagon-like peptide-1 (GLP-1) agonist; Amylin receptor agonist	Obesity	Pending (4Q 2026)	NDA
LY3502970 (obesity) (orforglipron)	Eli Lilly; Chugai	Oral	Glucagon-like peptide-1 (GLP-1) agonist	Obesity	Pending (1H 2026)	NDA

Wegovy is a GLP-1 receptor agonist (RA) that was initially approved in June 2021 for chronic weight management in adults with obesity or overweight with at least one weight-related comorbid condition. Since then, Wegovy has received four additional indications:

- December 2022: Approved in pediatric patients 12 years of age and older with obesity.
- March 2024: Approved to reduce the risk of major adverse cardiovascular events (MACEs), including CV death, nonfatal MI, and nonfatal stroke, in adults with established CVD and either obesity or overweight.
- August 2025: Approved for the treatment of adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced fibrosis, in combination with a reduced-calorie diet and increased physical activity.
- December 22, 2025: Oral formulation approved to reduce excess body weight and maintain long-term weight reduction in adults with obesity or in overweight adults in the presence of at least one weight-related comorbid condition and to reduce the risk of major adverse cardiovascular events (MACEs) in adults with established cardiovascular disease and either obesity or overweight.

Novo Nordisk has submitted a higher-dose 7.2 mg Wegovy (semaglutide) injection to the FDA for chronic weight management, utilizing the Commissioner's National Priority Voucher (CNPV) program for an expedited, 1–2 month review. The CNPV allows for a faster review time, with a decision expected shortly after the November 2025 filing, aiming for a potential early 2026 approval. Currently the only dose available is 2.4mg. The study, which evaluated the safety and efficacy of once-weekly semaglutide 7.2mg compared to placebo and semaglutide 2.4mg, as an adjunct to lifestyle intervention, in adults with obesity. Patients in the semaglutide 7.2mg dose achieved an average weight loss of 20.7% after 72 weeks compared to a reduction of 17.5% with semaglutide 2.4mg and 2.4% with placebo, when patients adhered to treatment. Additionally, 33.2% of those who received semaglutide 7.2 mg achieved a weight loss of 25% or more after 72 weeks, compared to 16.7% with semaglutide 2.4 mg and 0.0% with placebo. When assessed to include those who discontinued, people treated with semaglutide 7.2 mg achieved weight loss of 18.7% compared to a reduction of 15.6% with semaglutide 2.4 mg and 3.9% with placebo. 90.7% of participants taking semaglutide 7.2 mg achieved a body weight reduction of greater than or equal to 5%, compared to 89.9% and 36.8% for semaglutide 2.4 mg and placebo, respectively. Also, 31.2% of those who received semaglutide 7.2 mg achieved a weight loss of 25% or more after 72 weeks, compared to 15.3% for semaglutide 2.4 mg and 0.0% for placebo. Safety and tolerability for the higher dose was comparable to the 2.4mg dose.

The cost is estimated to be similar to other indications around $17,500 per year.

CagriSema is a combination product of semaglutide and novel amylin analogue, cagrilintide, to be used with a reduced-calorie diet and increased physical activity, to reduce excess body weight and maintain weight reduction long term in adults with obesity or overweight in the presence of at least one weight-related comorbid condition.

One trial evaluated the safety and efficacy of once-weekly CagriSema compared to semaglutide 2.4mg alone, cagrilintide 2.4mg alone, or placebo, all as an adjunct to lifestyle intervention in adults with obesity (BMI ≥30 kg/m2) or overweight (BMI ≥27 kg/m2) with one or more obesity-related complications and without diabetes, and the second trial evaluated the efficacy and safety of once-weekly CagriSema versus placebo, as an adjunct to lifestyle intervention in adults with type 2 diabetes and either obesity (BMI ≥30 kg/m2) or overweight (BMI ≥27 kg/m2).

The results from the first trial, which evaluated the treatment effect regardless of whether patients stayed on treatment, showed that patients treated with CagriSema achieved weight loss of 20.4% at 68 weeks versus 3.0% for the placebo group, 16.1% in the semaglutide 2.4mg group and 11.8% in the cagrilintide 2.4mg group. Weight loss of 25% or more was demonstrated in 40.4% of patients who received CagriSema vs 6.0%, 16.2%, and 0.9% of those who received cagrilintide 2.4mg, semaglutide 2.4mg, and placebo, respectively. When evaluating the treatment effect if all patients stayed on treatment, the CagriSema group had a weight loss of 22.7% at 68 weeks versus 2.3% in the placebo group, 11.5% in the cagrilintide 2.4mg group, 14.9% in the semaglutide 2.4mg group. Additionally, 91.9% of participants taking CagriSema achieved a body weight reduction of greater than or equal to 5%, compared to 31.5% for the placebo group. A supportive secondary analysis showed that about half (54%) of trial participants with obesity at baseline treated with CagriSema reached the threshold for non-obesity (BMI <30 kg/m2) at week 68. In the placebo group, 11.1% reached that threshold at 68 weeks.

In the head-to-head REDEFINE 4 trial, 809 adults with obesity and at least one weight-related comorbidity were randomized to receive once-weekly subcutaneous injections of either CagriSema or Zepbound. Results demonstrated that CagriSema achieved an average of 23% weight loss after 84 weeks of treatment; however, the drug failed on the primary endpoint of the trial, which was to show non-inferiority to Zepbound, which achieved a 25.5% weight loss.

If approved, it would become the first injectable GLP-1 receptor agonist and amylin analogue combination treatment with an estimated annual cost between $10,000 - $18,000.

Orforglipron is an investigational, once-daily oral GLP-1 receptor agonist being evaluated for the treatment of chronic weight management and type 2 diabetes.

The results from the trial, which included non-diabetic patients with obesity or overweight with obesity-related complications such as hypertension, received either placebo or one of three daily doses (6mg, 12mg, 36mg) of orforglipron, in addition to a healthy diet and physical activity. Over 72 weeks, patients in the low-, medium- and high-dose orforglipron groups lost an average of 7.8%, 9.3% and 12.4% of their initial body weight, respectively, compared to 2.1% for the placebo group. In comparison, Wegovy was evaluated for weight management in patients with obesity or overweight with at least one weight-related comorbidity. At week 64, patients who received Wegovy 25mg once daily achieved a mean weight reduction of 13.6% versus 2.4% of those taking placebo. In comparing the individual trials, Wegovy had a slightly higher decrease in weight compared to orforglipron, 13.5% vs 12.4%. Side effects were similar to other GLP-1 drugs: mild to moderate gastrointestinal symptoms such as nausea, vomiting and diarrhea.

Orforglipron will likely be the second oral GLP-1 based treatment available, after Wegovy. As a non-peptide-based drug, orforglipron does not have the mealtime dose restrictions that other GLP-1s have. Lilly was awarded the FDA Commissioner's National Priority Voucher for orforglipron, and it stated that it also has plans to submit orforglipron for obstructive sleep apnea in obesity/overweight in 2026. The estimated cost is $15,000 per year.

GLP-1 label expansion is expected, and other potential future uses and may include pending positive clinical trial results:

Drug	Indication if Approved
Rybelsus	Type 2 Diabetes-Higher Doses (Phase III)
Ozempic	Peripheral Arterial Disease (Pending)
Mounjaro	Reduce cardiovascular mortality in patients with type 2 diabetes (Pending) Improve glycemic control in type 1 diabetes (Phase III)
Zepbound	Non-alcoholic steatohepatitis (NASH) (Phase II) Non-alcoholic fatty liver disease (NAFLD) (Phase III) Chronic Kidney Disease (Phase II) Obesity (Phase III)

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Hepcludex (bulevirtide)	Gilead; MYR Pharmaceuticals	Subcutaneous	Antiviral	Hepatitis D	Pending (1H 2026)	Gilead; MYR Pharmaceuticals

Hepcludex is currently being evaluated for the treatment of chronic hepatitis delta (HDV) infection in adults.

Hepatitis delta, also called hepatitis D or HDV, is a liver infection caused by the hepatitis delta virus and represents the most severe form of viral hepatitis in humans. It occurs only in individuals who are already infected with hepatitis B, as the hepatitis delta virus relies on the hepatitis B virus to replicate. Treatment is typically a pegylated interferon-alpha given for 48 weeks, however it has limited efficacy and high relapse rates. Additionally, pegylated interferon-alpha is not formally FDA-approved specifically for chronic hepatitis D but is widely used off-label as a standard-of-care.

Hepcludex was evaluated in a study in which participants were randomized to one of three groups: no antiviral treatment for 48 weeks followed by 10mg daily of bulevirtide for 96 weeks, 2mg daily of bulevirtide, or 10mg daily of bulevirtide. Participants in the 2mg and 10mg bulevirtide group received the drug for 144 weeks. Results showed that 36% of adults with chronic HDV treated with bulevirtide 2mg or 10mg maintained virologic suppression for almost 2 years after stopping treatment after achieving undetectable HDV RNA at end of treatment. In participants who sustained undetectability for one year after end of therapy, no relapses occurred in the second year of follow-up.

If approved, it will be the first FDA drug approved for the treatment of hepatitis D with an estimated yearly cost between $100,000 - $200,000 per year.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Hympavzi (marstacimab)	Pfizer	Subcutaneous	Tissue factor pathway inhibitor (TFPI) antagonist	Hemophilia A or B	Pending (2Q 2026)	sBLA

Hympavzi is currently being evaluated in the treatment of adults and adolescents with hemophilia A or B with inhibitors. It was previously approved in 2024 for the treatment of adults and adolescents with hemophilia A or B without inhibitors.

Hemophilia is a disease that interferes with the normal coagulation process. This causes bleeding into soft tissue, joints, and internal organs. It can also cause severe bleeding and death in traumatic incidences. The two most common types of hemophilia are hemophilia A, which is the lack of factor VIII (FVIII), and hemophilia B, which is the lack of factor IX (FIX). Hemophilia inhibitors are antibodies developed by the immune system that neutralize clotting factor concentrates, rendering standard treatment ineffective and making bleeding hard to control. Of the more than 800,000 people in the world living with hemophilia A or hemophilia B, approximately 20% of people with hemophilia A and 3% of people with hemophilia B are unable to continue taking factor replacement therapies because they develop inhibitors to FVIII (Factor VIII) and FIX (Factor IX).

Hympavzi is the first anti-tissue factor pathway inhibitor (anti-TFPI) approved for the treatment of hemophilia A or B. It is also the first non-factor and SC prophylactic therapy for people with hemophilia B and the first treatment administered as a prefilled, autoinjector pen for people with hemophilia A or B. Instead of replacing a clotting factor like most hemophilia treatments, Hympavzi reduces the amount, and therefore, the activity of, naturally occurring TFPI. This increases the amount of thrombin that is generated, which is expected to reduce the frequency of or prevent bleeding episodes.

The trial evaluated the efficacy and safety of Hympavzi prophylaxis vs. and on-demand IV regimen with bypassing agents in 48 adults and adolescents with hemophilia A or B with inhibitors. Hympavzi was superior to on-demand treatment with a 93% reduction in annualized bleeding rate over 12 months. Superiority of Hympavzi was also demonstrated across all bleeding-related secondary endpoints which included spontaneous bleeds, joint bleeds, target joint bleeds, and total bleeds.

Hympavzi is a subcutaneous treatment option for hemophilia patients that would compete against Hemlibra (hemophilia A); Alhemo and Qfitlia (hemophilia A and B); and factor products. If approved for the pediatric population, which is currently being investigated, it would become the first non-factor prophylactic treatment available for children aged 6 to 11 years with hemophilia B.

The estimated cost is approximately $820,000 per year.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Tryngolza (olezarsen Sodium)	Ionis Pharmaceuticals; Akcea	Subcutaneous	Apolipoprotein inhibitor	Hypertriglyceridemia	Pending (06/2026)	sNDA

Tryngolza is currently being evaluated as an adjunct treatment to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia. It was previously approved in 2024 for adults with familial chylomicronemia syndrome.

Tryngolza helps reduce a protein called apoC-III. Reducing apoC-III protein helps clear excess triglycerides from the body. Elevated levels correlate with high triglyceride levels that have been associated with metabolic abnormalities, such as insulin resistance and/or metabolic syndrome as well as elevated cardiovascular event risk.

Two studies evaluated the safety and efficacy of Tryngolza in adults. In both trials, Tryngolza was tested at 80mg and 50mg doses, injected monthly. The trials achieved their primary endpoints, showing placebo-adjusted reductions of 55% and 72% in patients' triglyceride levels after six months of treatment. Additional data from the trials also showed secondary endpoint that Tryngolza reduced the risk of acute pancreatitis (AP) events by 85% after patients were on Tryngolza for a year.

If approved, SC olezarsen, has the potential for use as an add on to standard of care in patients with TGs ≥ 500 mg/dL and history of AP; patients with TGs ≥ 500 mg/dL and comorbidities and patients with TGs ≥ 880 mg/dL. Olezarsen would be the first FDA approved antisense oligonucleotide designed to inhibit the expression of APOC3 for the treatment of severe hypertriglyceridemia (sHTG).

The annual cost for FCS is approximately $600,000; and this estimate may cause the manufacturer to reassess pricing for this potential new indication.

Brand (Generic)	Manufacturer	Route	Mechanism of Action	Indication	Stage	Submission Type
Atacicept (atacicept)	EMD Serono (Merck KGaA); ZymoGenetics; Vera Therapeutics	Subcutaneous	Anti-B-cell activating factor (BAFF) antibody; Anti-a proliferation-inducing ligand (APRIL) antibody	IgA nephropathy	Pending (07/07/2026)	BLA

Atacicept is an investigational dual B-cell activating factor and a proliferation-inducing ligand (BAFF/APRIL) being evaluated for the treatment of IgA nephropathy in adults. BAFF (B-cell activating factor) and APRIL (a proliferation-inducing ligand) are two®® cytokines implicated in the pathogenesis of IgAN.

Immunoglobulin A nephropathy (IgAN) is an autoimmune disorder of the kidneys characterized by the buildup of immunoglobulin A (IgA) in the glomeruli, the structures responsible for filtering blood. This accumulation interferes with normal kidney function, allowing blood and protein to pass into the urine. Although the exact cause of IgAN remains unclear, the condition is thought to develop when the body produces structurally abnormal IgA proteins that are mistakenly identified as foreign. The immune system then mounts a response against these proteins, leading to the formation of immune complexes that deposit in the kidneys and trigger inflammation and tissue damage. During active infections—most often respiratory infections—the circulation and deposition of these IgA complexes in the kidneys increase.

The trial evaluated treatment with atacicept 150mg compared to placebo once weekly. The primary endpoint was the change in 24-hour urine protein-to-creatinine ration (UPCR) at 36 weeks. Findings showed that treatment with atacicept led to a 46% reduction in proteinuria with a significant reduction of 42% in UPCR compared to placebo.

If approved, Atacicept would become the sixth therapy approved for IgAN, joining Tarpeyo® (budesonide), Filspari® (sparsentan), Fabhalta® (iptacopan), Vanrafia® (atrasentan), and Voyxact® (sibeprenlimab). As the first dual BAFF/APRIL inhibitor in this setting, atacicept would offer a differentiated mechanism compared with Voyxact's anti-APRIL–only approach, although the clinical significance of dual pathway inhibition has yet to be established. In terms of administration, atacicept is given as a once-weekly subcutaneous injection, whereas Voyxact is dosed subcutaneously once every four weeks.

In light of the updated September 2025 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, the anti-APRIL and anti-APRIL/BAFF therapies are expected to compete most directly with Tarpeyo and likely Fabhalta.

The estimated yearly cost is between $300,000 - $500,000.

GENE THERAPY

Gene therapies work by replacing or modifying the disease-causing gene to treat or cure a disease. While only a small number of diseases are currently treatable with gene therapies, there are more than 500 gene therapies undergoing research to make sure they are safe and effective.

Recent FDA Approvals

Waskyra® (etuvetidigene autotemcel) / Fondazione Telethon ETS

Route	Mechanism of Action	Proposed Indication	Approval (PDUFA) Date	Projected Estimated Cost
Autologous ex vivo infusion	Gene Therapy	Wiskott-Aldrich Syndrome	12/9/2025	Estimated $3.0–$3.5M per one-time treatment

On December 9, 2025, the U.S. Food and Drug Administration approved Waskyra® (etuvetidigene autotemcel) as the first cell-based gene therapy for the treatment of Wiskott-Aldrich syndrome (WAS). Waskyra is indicated for pediatric patients aged 6 months and older and adults with a confirmed mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate but a suitable HLA-matched related donor is unavailable. WAS is a rare, life-threatening, X-linked primary immunodeficiency characterized by thrombocytopenia, recurrent infections, eczema, immune dysregulation, autoimmunity, and an increased risk of hematologic malignancies. Prior to this approval, treatment options were limited to supportive care or allogeneic HSCT, which is donor-dependent and associated with significant risks.

Waskyra consists of the patient's own CD34+ hematopoietic stem cells that are genetically modified ex vivo using a lentiviral vector encoding a functional WAS gene. The gene corrected cells are infused intravenously, where they engraft and restore WAS protein expression across immune cell lineages. By correcting the underlying genetic defect, Waskyra improves immune function, increases platelet counts, and reduces infection and bleeding risk.

Approval was supported by data from two open-label, single-arm, multinational clinical studies and an expanded access program that collectively enrolled 27 patients with severe WAS. Across studies, treatment with Waskyra resulted in clinical benefit with severe infections being reduced by 93% during the 6- to 18-month post-treatment period compared with the year prior to therapy, while moderate to severe bleeding events were reduced by 60% in the first 12 months following treatment. The majority of patients remained free from moderate or severe bleeding events through four years of follow-up.

The most common adverse events observed included rash, respiratory tract infection, febrile neutropenia, catheter-related infection, vomiting, diarrhea, liver injury, and petechiae. Safety findings were consistent with conditioning-related toxicities.

Waskyra is administered as a single-dose intravenous infusion.

Gene Pipeline

The following gene therapies could be approved within the next 12 months.

Clemidsogene lanparvovec (RGX-121) / Regenxbio

Route	Mechanism of Action	Proposed Indication	Approval (PDUFA) Date	Projected Estimated Cost
Intracisternal / Intrathecal	Gene Therapy	Hunter syndrome	TBD	$2M–$3M (One time)

Hunter syndrome (MPS II) is a rare, X-linked lysosomal storage disorder caused by a deficiency of iduronate-2-sulfatase (IDS). Without IDS, glycosaminoglycans (GAGs) accumulate throughout the body and brain, leading to multi-organ disease, neurocognitive decline, airway obstruction, cardiac disease, and premature death. Current enzyme replacement therapies (ERTs) improve somatic symptoms but do not cross the blood–brain barrier, leaving neurological manifestations untreated.

Clemidsogene lanparvovec (RGX-121) is a one-time AAV9 gene therapy designed to address both somatic and neurological disease by delivering a functional copy of the IDS gene to cells in the central nervous system and periphery, enabling endogenous IDS enzyme production and reducing GAG accumulation.

Interim data from Phase I/II/III trials have shown reductions in CSF and plasma GAGs, sustained IDS enzyme activity, and trends toward stabilization of neurocognitive function compared with natural history. Patients demonstrated improved biomarker profiles consistent with therapeutic effect. Safety to date has been favorable, with no unexpected serious adverse events reported. Additionally, new 12-month pivotal data released in September 2025 showed greater than 80% reductions in CSF heparan sulfate disaccharide D2S6 (HS-D2S6), continued IDS enzyme activity, and sustained neurodevelopmental stability. No new safety issues emerged during the 12-month follow-up.

The FDA accepted the BLA under Priority Review with an original PDUFA date of November 9, 2025, later extended to February 8, 2026 to allow review of additional long-term data. On February 8, 2026, the FDA issued a Complete Response Letter (CRL) for RGX-121, rejecting the application for accelerated approval. The FDA cited concerns regarding the ability of the clinical trial to adequately define the patient population, reliance on a natural history control arm, and the use of heparan sulfate as a surrogate biomarker endpoint. The CRL did not cite manufacturing deficiencies or new safety concerns related to RGX-121.

The FDA acknowledged a recent clinical hold involving Regenxbio's separate Hurler syndrome gene therapy (RGX-111) following identification of a brain tumor in a treated patient; however, the FDA stated this event was not a basis for the RGX-121 rejection.

Regenxbio has stated that it plans to resubmit the BLA with additional long-term clinical data following engagement with the FDA. If approved, RGX-121 would be the first gene therapy for Hunter syndrome, offering a single-dose treatment that addresses both systemic and neurological disease manifestations.

Kresladi (marnetegragene autotemcel)/Rocket

Route	Mechanism of Action	Proposed Indication	Approval (PDUFA) Date	Projected Estimated Cost
Intravenous	Gene Therapy	Primary immunodeficiency; severe leukocyte adhesion deficiency	3/28/2026	$3M - $3.5M

Severe Leukocyte Adhesion Deficiency-I (LAD-I) is a rare pediatric disease caused by mutations in the ITGB2 gene, which encodes the CD18 protein essential for normal leukocyte adhesion and immune response. Children with LAD-I experience severe, recurrent bacterial and fungal infections that respond poorly to antibiotics and antifungal therapies. Those who survive infancy often develop pneumonia, mouth ulcers, necrotic skin lesions, and bloodstream infections. LAD-I affects an estimated 800–1,000 children across the United States and Europe. The only potentially curative treatment is allogeneic stem cell transplantation, which carries substantial morbidity and mortality; without a successful transplant, survival beyond childhood is rare.

Marnetegragene is an investigational one-time autologous gene therapy that uses patient-derived stem cells genetically modified to deliver a functional copy of the ITGB2 gene. In a global Phase I/II study, marnetegragene demonstrated 100% overall survival at 12 months and throughout the 12–24 months of follow-up in all nine treated patients. Large reductions in clinically significant infections were observed compared with pretreatment history, along with resolution of LAD-I–related skin lesions and restoration of wound repair capability. The therapy was well tolerated, with no serious treatment-related adverse events reported.

The FDA first accepted the BLA for Kresladi with Priority Review in October 2023. In June 2024, the FDA issued a Complete Response Letter (CRL) requesting additional Chemistry, Manufacturing, and Controls (CMC) information. The company resubmitted the BLA in October 2025, and the FDA has assigned a new PDUFA action date of March 28, 2026, marking the second full review cycle for Kresladi.

CELL THERAPY

Cell therapy works to treat diseases by restoring or altering certain sets of cells or by using cells to carry a therapy through the body. With cell therapy, cells are cultivated or modified outside the body before being injected into the patient. The cells may originate from the patient or a donor.

Recent FDA Approvals

Tabelecleucel (Ebvallo®)/Atara Biotherapeutics, Inc.

Route	Mechanism of Action	Proposed Indication	Approval (PDUFA) Date	Projected Estimated Cost
Intravenous	Cell Therapy	Relapsed/refractory Epstein-Barr Virus-Positive Posttransplant Lymphoproliferative Disease	1/10/2026	$1.5 million - $2.5 million annually

On January 10, 2026, the U.S. Food and Drug Administration approved Ebvallo® (tabelecleucel) as the first allogeneic EBV-specific T-cell therapy for the treatment of relapsed or refractory Epstein-Barr virus–positive post-transplant lymphoproliferative disease (EBV+ PTLD). EBV+ PTLD is a complication that can occur following solid organ transplantation, resulting from the reactivation of EBV in immunosuppressed patients. EBV is a common virus that typically remains dormant in the body after an initial infection, but in transplant recipients, the immunosuppressive medications used to prevent organ rejection can impair the body's ability to control the virus. This leads to abnormal proliferation of B lymphocytes, which may progress to lymphoma or other forms of cancer. The condition most commonly affects individuals who are EBV seronegative prior to transplantation and receive an EBV-positive organ, increasing their susceptibility to the disease.

Management involves reducing the levels of immunosuppressive therapy to allow for immune recovery. Additional treatments may include antiviral therapies and targeted immunotherapies, such as rituximab.

Tabelecleucel (Ebvallo) is an allogeneic EBV-specific T-cell immunotherapy aimed at treating relapsed/refractory EBV+ PTLD by utilizing donor-derived T-cells that are specifically engineered to target and attack cells infected with EBV.

In May 2024, Atara Biotherapeutics submitted a BLA to the FDA for tabelecleucel. In December 2024, updated results from the phase III ALLELE clinical trial were presented at the 66th American Society of Hematology Annual Meeting. The study included 75 patients with the primary endpoint being the overall response rate (ORR), along with secondary endpoints of duration of response (DOR), overall survival (OS), and time to response (TTR). The study found that tabelecleucel achieved a 51% ORR and a 28% complete response rate with a median DOR of 23 months and median OS of 18.4 months. Safety results were consistent with prior studies, with no reports of cytokine release syndrome, tumor flare reactions, or graft vs. host disease.

However, on January 16, 2025, the FDA issued a complete response letter (CRL) regarding the BLA. The CRL was related to observations as part of a standard pre-license inspection of a third-party manufacturing facility for Ebvallo. As a result, the FDA halted trials of Ebvallo due to the compliance issues found at the third-party manufacturing facility. A temporary clinical hold was placed on the ALLELE trial related to these manufacturing compliance issues. In May 2025, the FDA lifted the clinical hold on the Phase III ALLELE trial, allowing development to resume. Atara resubmitted the BLA in July 2025 and the FDA accepted it under Priority Review.

The Institute for Clinical and Economic Review (ICER) evaluated tabelecleucel and concluded that current evidence indicates tabelecleucel has a net health benefit compared to standard of care, extending survival in patients with relapsed or refractory EBV+ PTLD. The therapy was deemed cost-effective if priced between $143,900 and $273,700 per treatment cycle, however pricing has not yet been disclosed.

Ebvallo has already been approved in Europe in December 2022 for treating relapsed/refractory EBV+ PTLD in patients aged 2 years and older.

Cell Pipeline

The following gene therapies could be approved within the next 12 months.

Deramiocel (CAP-1002) / Capricor Therapeutics

Route	Mechanism of Action	Proposed Indication	Approval (PDUFA) Date	Estimated Cost
Intravenous	Cell Therapy	Duchenne muscular dystrophy cardiomyopathy	TBD	$750,000 annually

Deramiocel (CAP-1002) is an investigational allogeneic cell therapy indicated for Duchenne muscular dystrophy (DMD). DMD is a progressive X-linked neuromuscular disorder caused by mutations in the DMD gene, which encodes dystrophin, a protein essential for muscle stability. As the disease advances, cardiac muscle is increasingly affected, leading to DMD-associated cardiomyopathy.

Current treatment of DMD cardiomyopathy includes corticosteroids and cardioprotective medications, which may slow progression but do not directly target the underlying myocardial pathology. Deramiocel is composed of cardiosphere-derived cells (CDCs), a type of stromal cell harvested from donor heart tissue. These cells exert therapeutic effects via paracrine signaling, including the release of extracellular vesicles that promote anti-inflammatory and anti-fibrotic effects in damaged myocardium.

In March 2025, Capricor Therapeutics announced that the FDA had accepted its Biologics License Application (BLA) for deramiocel for the treatment of DMD-associated cardiomyopathy and granted it Priority Review. In July 2025, the FDA issued a Complete Response Letter (CRL), stating that the application did not demonstrate sufficient evidence of effectiveness and that certain Chemistry, Manufacturing, and Controls (CMC) issues remained unresolved. In August 2025, Capricor reported that inspection findings had been resolved. However, no new PDUFA date has been assigned. The company intends to resubmit the BLA after incorporating additional data from the ongoing Phase 3 HOPE-3 trial, with updated results expected in 2026.

The BLA is supported by data from the Phase 2 HOPE-2 study, which evaluated the safety and efficacy of deramiocel in DMD patients. In HOPE-2, 8 patients were assigned to deramiocel and 12 to placebo. The mean 12-month change from baseline in mid-level elbow function favored deramiocel (percentile difference 36.2%; 95% CI 12.7–59.7; difference 2.6 points; P = .014). Individuals who received deramiocel had an average 1.2% improvement in left ventricular ejection fraction (LVEF), with a more pronounced 3.0% increase among patients with baseline LVEF ≥45%. Reductions in left ventricular end-systolic volume (LVESV) and end-diastolic volume (LVEDV) indicated favorable cardiac remodeling.

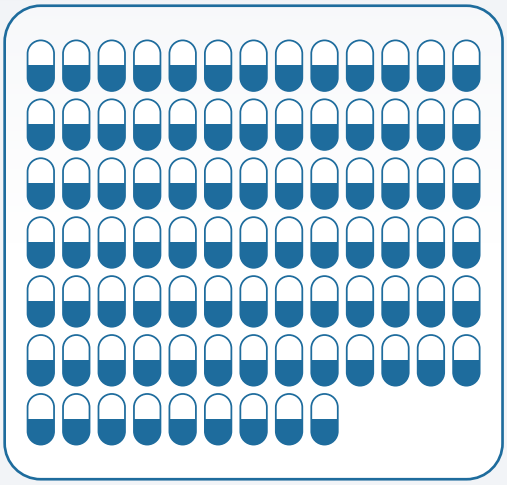
Following HOPE-2, eligible participants who wished to continue treatment entered the open-label extension (OLE) study, receiving deramiocel every 3 months. Over three years, treated patients demonstrated a 3.7-point gain on the Performance of Upper Limb (PUL) scale versus external controls, indicating a slowing of skeletal muscle decline.

In January 2026, Capricor provided a regulatory update indicating that the FDA has requested submission of the full Phase 3 HOPE-3 clinical study report and supporting datasets for deramiocel. The FDA did not request any new clinical trials or additional patient enrollment.

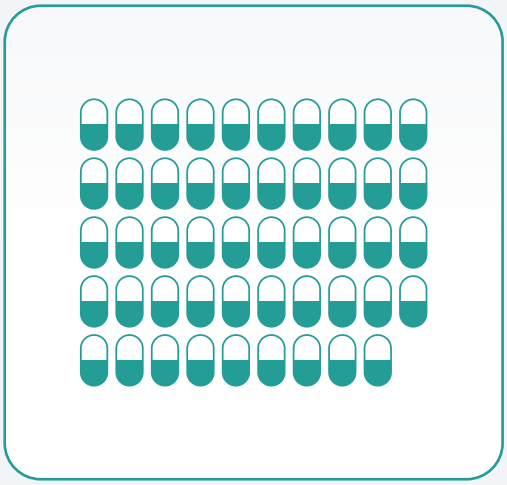
Capricor plans to submit the complete HOPE-3 clinical study report to the FDA in early 2026. Following this submission, the FDA is expected to determine whether to assign a new PDUFA action date based on review of the HOPE-3 data package. If approved, deramiocel would become the first cell therapy specifically indicated for DMD-associated cardiomyopathy and would be administered quarterly as a long-term treatment.

Biosimilars Pipeline

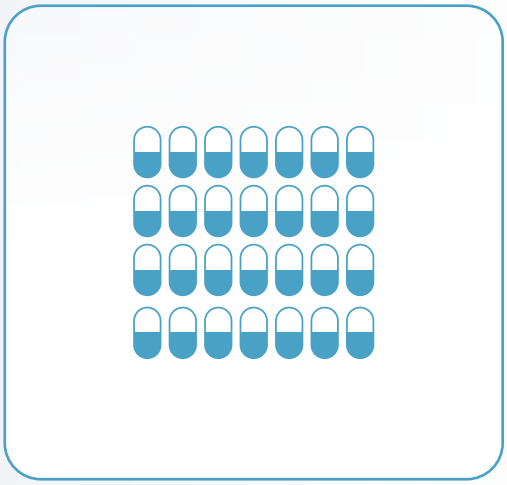
QUICK FACTS



87 FDA Approved Biosimilars to Date



49 Launched Biosimilars



28 Approved Interchangeable Biosimilars

The U.S. Food and Drug Administration has proposed that biosimilar drugs seeking agency's interchangeable designation will no longer need studies showing the impact of switching between them and the branded drug. There have been no changes or updates to this proposal and the draft guidance remains the current status quo while awaiting finalization. This continues having biosimilars being able to gain an interchangeable designation while others are not seeking this labeling.

Recent FDA Approvals

FDA approves Filkri™ (filgrastim-laha), a biosimilar to Neupogen®

On February 18, 2026, the U.S. Food and Drug Administration approved Filkri (filgrastim-laha), a biosimilar to Neupogen (filgrastim), for the treatment of neutropenia. Filkri is indicated for patients with cancer receiving myelosuppressive chemotherapy, patients undergoing bone marrow transplantation, patients with acute myeloid leukemia (AML) receiving induction or consolidation therapy, patients with severe chronic neutropenia, and patients acutely exposed to myelosuppressive doses of radiation. Neutropenia is a common and serious complication of chemotherapy and radiation exposure that increases the risk of infection and treatment-related morbidity.

Filkri belongs to the granulocyte colony-stimulating factor (G-CSF) class, a group of recombinant biologics that stimulate the production, maturation, and activation of neutrophils in the bone marrow. By increasing neutrophil counts, G-CSF therapies reduce the duration and severity of neutropenia and lower the risk of infection in vulnerable patient populations.

Approval of Filkri was supported by results from two randomized clinical studies conducted in healthy adults. Filkri demonstrated similar safety, immunogenicity, and biologic activity to Neupogen, with no clinically meaningful differences observed.

Filkri is administered as a short-acting subcutaneous or intravenous injection and is supplied as single-dose prefilled syringes in 300 mcg/0.5 mL and 480 mcg/0.8 mL strengths. No launch date or pricing information has been announced at this time.

FDA Approves Nufymco® (ranibizumab-leyk), Third Biosimilar to Lucentis

On December 23, 2025, the U.S. Food and Drug Administration approved Nufymco (ranibizumab-leyk), a biosimilar to Lucentis® (ranibizumab). Ranibizumab is a humanized monoclonal antibody fragment that binds vascular endothelial growth factor A (VEGF-A), inhibiting abnormal angiogenesis and vascular permeability in the retina. Nufymco is approved for the treatment of neovascular (wet) age-related macular degeneration, diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

Previous ranibizumab biosimilars include Byooviz® (ranibizumab-nuna) and Cimerli® (ranibizumab-eqrn), the first interchangeable biosimilar to Lucentis. Nufymco was approved as an interchangeable biosimilar, making it the second interchangeable biosimilar to Lucentis.

Approval was supported by a comprehensive biosimilarity program demonstrating no clinically meaningful differences from Lucentis with respect to safety, efficacy, pharmacokinetics, and immunogenicity. The safety profile of Nufymco is consistent with reference ranibizumab. Nufymco is administered as an intravitreal injection and is available in 6 mg/mL and 10 mg/mL formulations.

FDA Approves Boncresa™ (denosumab-mobz) and Oziltus™ (denosumab-mobz), Biosimilars to Prolia® and Xgeva®

On December 22, 2025, the U.S. Food and Drug Administration approved Boncresa (denosumab-mobz), a biosimilar to Prolia (denosumab), and Oziltus (denosumab-mobz), a biosimilar to Xgeva (denosumab). Denosumab is a human monoclonal antibody that binds to receptor activator of nuclear factor kappa-B ligand (RANKL), inhibiting osteoclast formation, function, and survival, thereby reducing bone resorption.

Boncresa is approved for the following indications: treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Oziltus is approved for the following indications: prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Approval of Boncresa and Oziltus was supported by data from a phase 1 randomized study comparing denosumab-mobz with reference denosumab (Xgeva) in healthy male participants, and a phase 3 randomized study comparing denosumab-mobz with Prolia in postmenopausal women with osteoporosis. In both studies, denosumab-mobz demonstrated comparable safety, efficacy, tolerability, and immunogenicity to the respective reference products, with no clinically meaningful differences observed.

Boncresa is supplied as a 60 mg/mL single-dose prefilled syringe for subcutaneous injection, while Oziltus is supplied as a 120 mg/1.7 mL single-dose vial for subcutaneous injection.

FDA Approves Armlupeg™ (pegfilgrastim-unne), a Biosimilar to Neulasta®

On December 1, 2025, the U.S. Food and Drug Administration approved Armlupeg (pegfilgrastim-unne), a biosimilar to Neulasta (pegfilgrastim), for subcutaneous administration. Armlupeg is indicated to reduce the risk of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. It is also indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Pegfilgrastim is a long-acting granulocyte colony-stimulating factor (G-CSF) that stimulates the production, maturation, and activation of neutrophils in the bone marrow. By increasing absolute neutrophil counts, pegfilgrastim reduces the duration and severity of neutropenia and lowers the risk of infection in patients receiving chemotherapy or following radiation exposure.

FDA approval of Armlupeg was based on a totality-of-evidence approach demonstrating biosimilarity to reference pegfilgrastim, including analytical characterization, pharmacokinetic and pharmacodynamic comparability, and safety and immunogenicity assessments. No clinically meaningful differences were identified between Armlupeg and the reference product. Armlupeg demonstrated comparable safety to reference pegfilgrastim, with expected G-CSF class effects such as bone pain and rare serious risks including splenic rupture and hypersensitivity.

Armlupeg is supplied as a 6 mg/0.6 mL single-dose prefilled syringe for subcutaneous injection.

Upcoming Biosimilars

Lucamzi™- Biosimilar to Lucentis®

In May 2024, Xbrane Biopharma and STADA Arzneimittel announced a partnership with Valorum Biologics to commercialize Lucamzi (ranibizumab), a biosimilar to Lucentis. Ranibizumab is an anti-VEGF (vascular endothelial growth factor) monoclonal antibody fragment used in the treatment of serious retinal disorders, including neovascular (wet) age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO).

Clinical data supporting Lucamzi demonstrated no clinically meaningful differences in efficacy, safety, immunogenicity, or pharmacokinetic profile compared with the reference product ranibizumab. Although therapeutic equivalence to Lucentis was confirmed across phase III and pharmacokinetic studies, Lucamzi does not carry an FDA interchangeability designation.

The FDA initially set an action date of October 21, 2025, for Lucamzi's BLA resubmission; however, they issued a Complete Response Letter (CRL) on October 19, 2025, citing unresolved manufacturing-site observations identified during re-inspection of a contract manufacturing facility. No issues were raised regarding the clinical or analytical components of the BLA.

Xbrane has since announced that it will re-submit the BLA in March 2026 following completion of corrective actions, with an anticipated six-month review timeline. As a result, the projected approval date is now expected in September 2026. If approved, Lucamzi would join Byooviz, Cimerli and Nufymco as biosimilars to Lucentis.

BAT2506™ – Biosimilar to Simponi®

In July 2025, Bio-Thera Solutions and Accord BioPharma announced that the FDA had accepted Biologics License Application (BLA) for BAT2506, a proposed biosimilar to Simponi (golimumab). Golimumab is a tumor necrosis factor (TNF) inhibitor used for the treatment of rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, and ankylosing spondylitis.

The BLA for BAT2506 is supported by a comprehensive data package, including analytical, pharmacokinetic, safety, and efficacy results comparing BAT2506 with the reference product. Data from a global phase III clinical trial in patients with rheumatoid arthritis demonstrated therapeutic equivalence, with no clinically meaningful differences observed in efficacy, safety, or immunogenicity.

This is the second FDA submission for a Simponi biosimilar, following Alvotech and Teva's filing in January 2025. The application for BAT2506 also includes a request for the product to be designated as an interchangeable biosimilar. The estimated approval date is May 16, 2026.

GP40141 – Biosimilar to Nplate®

On August 25, 2025, new clinical data published in EJHaem showed that the romiplostim biosimilar candidate GP40141 demonstrated therapeutic equivalence to reference romiplostim (Nplate®) for the treatment of immune thrombocytopenia (ITP). Romiplostim, a thrombopoietin receptor agonist (TPO-RA), is widely used to stimulate platelet production in patients with persistent or chronic ITP.

The multicenter, single-blind, randomized controlled phase 3 trial evaluated GP40141 in 136 adults with persistent or chronic ITP. Patients were randomized 1:1 to receive either GP40141 or reference romiplostim for 26 weeks. The primary end point was the proportion of patients achieving a platelet response (≥50 × 10^9/L) at week 11. GP40141 met the predefined equivalence criteria: 78% of patients in the GP40141 group achieved a platelet response compared with 85% in the reference group. Durable platelet response rates, bleeding events, and overall safety outcomes were also comparable.

Adverse events occurred in 22 patients receiving GP40141 and 18 patients receiving the reference product, with no significant difference in the frequency or severity of AEs. The most common adverse event was petechiae, followed by mucosal bleeding.

If approved, GP40141 would become the first biosimilar to romiplostim. No FDA submission or anticipated approval date has been announced yet.

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ABOUT ASCELLAHEALTH

AscellaHealth is a mission-driven, global healthcare company focused on solving challenges across the complex specialty and retail pharmaceutical ecosystem—always with patients at the center of what we do. We partner with payers, pharmaceutical manufacturers, and healthcare stakeholders to improve access to critical therapies through technology-enabled solutions that span the full pharmaceutical lifecycle, from commercialization and specialty pharmacy to care coordination, distribution, and pharmacy management. Supporting more than 450 health partners and 1.2 million patients worldwide, our work makes a meaningful difference every day.

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