carelon Rx

Drug and biologic pipeline update Q3 2026

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CarelonRx's quarterly

Drug and biologic pipeline update

CarelonRx closely monitors the drug and biologic pipeline as part of our mission to improve health, lower the total cost of care across pharmacy and medical, and deliver an exceptional experience for our clients and members. Pipeline monitoring and intelligence help support evidence-based, clinically appropriate use of drugs and therapies at launch. In addition, future cost impact estimates provide valuable insights to guide health plan and client planning.

Our Q3 2026 update highlights three agents in late-stage development:

- Brepocitinib for dermatomyositis
- Imsidolimab for generalized pustular psoriasis (GPP) flares and maintenance
- Anitocabtagene autoleucel for multiple myeloma

You will also find an overview of other products that are expected to reach the market in the next 12 months and an update on gene therapies and biosimilars.

Emerging new therapies	3	Biosimilar pipeline update	12
Other significant product approvals	6	Gene therapies in the pipeline	14

Emerging new therapies

Brepocitinib

Condition:
Dermatomyositis is a type of inflammatory autoimmune disease of the muscles and skin affecting about 25,000 to 50,000 adults in the United States. Average age of onset is between 40 and 60 years.

The major symptoms of dermatomyositis include muscle weakness and a "butterfly rash" on the upper eyelids, forehead, cheeks, and bridge of nose. Skin changes may be the only sign of dermatomyositis at the start in up to 40% of people. In severe cases, muscle weakness may affect the gastrointestinal tract, heart, blood vessels, or lungs and may become fatal. There may be an association with underlying cancer. Current treatments are directed toward specific symptoms and may vary among individuals.

Role in treatment:
If approved, brepocitinib could provide a targeted oral alternative to conventional therapies such as corticosteroids, off-label immunosuppressants, and intravenous immune globulin (IVIG), which currently dominate treatment management.

Food and Drug Administration (FDA)-approved therapies for dermatomyositis include: Cortef® (oral hydrocortisone), Depo-Medrol® and Solu-Medrol® (intravenous methylprednisolone), and Octagam® (IVIG). Corticotropin injection is also FDA approved to treat dermatomyositis, though use is limited and not recommended in current guidelines.

FDA-approved therapies for dermatomyositis remain limited, creating potential demand for targeted agents with improved efficacy and steroid-sparing potential.

Brepocitinib is designed to block the TYK2 and JAK1 pathways, which play a role in inflammation. Other agents that target TYK2 or JAK1 are not FDA approved for use in dermatomyositis.

Brepocitinib will also enter a competitive pipeline landscape that includes investigational interferon-targeted therapies (dazukibart, Saphnelo® SC) as well as expanded use of Vyvgart®/Vyvgart Hytrulo®, a neonatal Fc receptor blocker.

Efficacy:
The Biologics License Application (BLA) submitted to the FDA for dermatomyositis is supported by the phase 3 VALOR trial in adults with active dermatomyositis who had previously received at least one conventional therapy.

In the study, brepocitinib demonstrated superiority over placebo in improving both muscle and skin disease activity. Improvements were measured using validated dermatomyositis assessment tools, including Total Improvement Score (TIS) and Dermatomyositis Outcomes for Muscle and Skin (DMOMS).

Brepocitinib offers once-daily oral administration compared with injectable or infusion-based therapies currently used in refractory disease management.

Based on the results of the VALOR clinical trial, brepocitinib may be an alternative for those who do not respond to first-line therapy for dermatomyositis.

Safety:
Brepocitinib has been generally well tolerated in studies with rates of adverse events similar to placebo. The most common side effects were cold-like symptoms, urinary tract infection, nausea, diarrhea, and headache. Serious infections occurred more often with brepocitinib than placebo and resolved with medical management. Existing JAK inhibitors carry boxed warnings for serious infections, malignancy, cardiovascular events, thrombosis, and mortality. If brepocitinib is approved, final labeling will determine whether it shares this boxed warning.

Product:
Brepocitinib

Indication:
Dermatomyositis in adults

Estimated FDA approval:
August 2026

Therapeutic class:
Dual tyrosine kinase 2 (TYK2) and janus kinase 1 (JAK1) inhibitor

Route of administration:
Oral

FDA designations:
Orphan Drug; Priority Review

Manufacturer:
Priovant Therapeutics

Financial impact:
The cost of brepocitinib is unknown. Potential impact will likely depend on uptake among individuals with refractory disease, treatment duration, and the extent to which the therapy reduces corticosteroid exposure, disease flares, hospitalizations, and IVIG utilization. Potential future expanded uses, including uveitis and cicatricial (scarring) alopecia, may increase overall impact of brepocitinib.

CarelonRx view:
Brepocitinib will enter a market with limited FDA-approved options and substantial unmet need, particularly among individuals with refractory disease. Brepocitinib will offer a targeted once-daily oral treatment option for those inadequately controlled with current therapies. Long-term efficacy, durability of response, comparative effectiveness, and real-world safety outcomes will likely determine its ultimate place in therapy.

Emerging new therapies

Imsidolimab

Condition:
Generalized pustular psoriasis (GPP) is a rare, chronic, autoinflammatory disease that may occur with plaque psoriasis. GPP flares are marked by the sudden appearance of widespread sterile pustules, redness, pain, and systemic symptoms such as fever and fatigue. Severe flares may require hospitalization and can become life-threatening due to complications such as sepsis or cardiovascular failure.

Disease course varies among individuals. Some experience intermittent flares with symptom-free periods between episodes, while others have persistent pustules with periodic worsening. Flare frequency, severity, and duration are unpredictable. Most flares last 2 to 5 weeks, although some may persist for several months. Dysregulation of the interleukin-36 (IL-36) inflammatory pathway is a key driver of GPP and supports the use of IL-36-targeted therapies.

GPP is an ultra-rare disease, with estimated global prevalence ranging from approximately 2 to 124 cases per million, with regional variation. The condition can occur at any age, although the median age at diagnosis is approximately 50 years.

Role in treatment:
If approved, imsidolimab would be another IL-36 antagonist option for GPP alongside Spevigo® (IV or SC injection spesolimab-sbzo), which is FDA-approved for adults and pediatric individuals 12 years and older weighing at least 40 kg. Spevigo has labeled dosing for both treatment of active GPP flares with IV administration and treatment when not experiencing a flare with SC monthly dosing.

Imsidolimab is most likely to be used for those with confirmed GPP who require rapid control of acute flares, and for maintenance of response in those who are clear or nearly clear after induction.

Off-label use of other biologics targeting interleukin-17 (IL-17), interleukin-23 (IL-23), or related inflammatory pathways has been reported historically. However, pathway agents are more directly aligned with GPP pathophysiology. While future approvals could change where imsidolimab fits within the GPP treatment pathway, Spevigo is currently the most relevant comparator because it is the only approved IL-36-targeted therapy and would likely be the primary alternative.

Efficacy:
The BLA submitted to the FDA for GPP is supported by the phase 3 GEMINI trials in adults with active GPP.

GEMINI-1 enrolled 45 individuals. Imsidolimab demonstrated superiority over placebo as measured by the GPP Physician Global Assessment (GPPPGA). More individuals achieved clear or almost clear skin with imsidolimab compared to placebo.

GEMINI-2 enrolled GEMINI-1 responders, who were re-randomized to monthly maintenance with SC imsidolimab or placebo. All 8 individuals assigned to SC imsidolimab maintained clear or almost clear skin as measured by GPPPGA at 24 weeks and none experienced a flare; in the placebo arm, 25% maintained GPPPGA 0/1 and 63% experienced a flare.

Similar to data for Spevigo, the clinical trials included a small number of individuals due to the rarity of GPP, and caution should be used in interpreting the data. There are no head-to-head trials comparing imsidolimab to Spevigo.

Safety:
Across GEMINI-1 and GEMINI-2, no treatment-related serious adverse events or serious adverse events leading to discontinuation were reported in imsidolimab-treated individuals. Low anti-drug antibody incidence has been described as a potential differentiator from Spevigo. If confirmed in clinical practice, lower immunogenicity may support long-term treatment durability and sustained disease control, although no direct comparisons with Spevigo have been conducted.

Product:
Imsidolimab

Indication:
Generalized pustular psoriasis (GPP) in adults

Estimated FDA approval:
December 2026

Therapeutic class:
Interleukin-36 (IL-36) receptor antagonist

Route of administration:
Intravenous (IV) induction, subcutaneous (SC) maintenance

FDA designations:
Orphan Drug

Manufacturer:
Vanda Pharmaceuticals

Financial impact:
Imsidolimab pricing has not been announced but will likely be high, similar to other specialty biologics for rare diseases. Overall impact is not expected to be significant due to the low prevalence of GPP.

CarelonRx view:
If approved, imsidolimab may expand targeted treatment options for GPP by adding another IL-36 antagonist. Clinical differentiation from Spevigo will depend on the final FDA label, dose and dosage and dosage forms, comparative convenience, immunogenicity, durability, safety language, distribution channel, and launch price.

Emerging new therapies

Anitocabtagene autoleucel

Condition:
Multiple myeloma (MM) occurs when plasma cells, a type of white blood cell found in the bone marrow, begin to grow out of control. When this happens, there is less room for other blood-forming cells and can lead to a shortage of red blood cells, white blood cells and platelets causing anemia, leukopenia, and thrombocytopenia, respectively. Additional complications include increase in bone breakdown and infections, as well as kidney damage.

Individuals more likely to develop MM are those older than 65 years, men, Black people, or those who have a family history of MM, excess body weight, other plasma cell diseases, or have been exposed to radiation or certain chemicals. The National Cancer Institute estimates there will be about 36,000 new cases of MM diagnosed in the United States in 2026, and about 10,850 deaths from MM.

Role in treatment:
Treatment of MM is based on how advanced the disease is, whether the individual has symptoms, and how likely they will tolerate intense therapy. Treatment may consist of chemotherapy, stem cell transplantation, radiation, or targeted therapy. Initial treatment often consists of three or four drugs, including a proteasome inhibitor, a CD38-targeting monoclonal antibody, lenalidomide oral and dexamethasone oral, followed by autologous hematopoietic cell transplantation (HCT) in eligible individuals.

While most individuals will have an initial response to treatment, conventional therapy is not curative and MM will likely relapse. B-cell maturation antigen (BCMA)-targeted therapies are increasingly being used in individuals with relapsed or refractory MM, including after early relapse. CAR T-cell therapies Abecma® (idecabtagene vicleucel, intravenous; Bristol-Myers Squibb) and Carvykti® (ciltacabtagene autoleucel, intravenous; Janssen) are approved by the FDA for relapsed or refractory MM after 2 or more and 1 or more prior lines of therapy, respectively. CAR T-cell therapy is a complex process that requires leukapheresis for T-cell collection, lymphodepleting chemotherapy before CAR T-cell infusion, and specialized monitoring during and after treatment.

Anitocabtagene autoleucel (anito-cel) is an investigational autologous CAR T-cell therapy that, if approved, would join Abecma and Carvykti as an additional treatment option for relapsed or refractory MM. Like Abecma and Carvykti, anito-cel targets BCMA expressed on malignant plasma cells. However, anito-cel is the first BCMA-directed CAR T-cell therapy to utilize a D-Domain binder, a novel binding technology that may contribute to potent anti-myeloma activity and a differentiated safety profile.

Efficacy:
Interim data from the iMMagine-1 phase 2 study of 117 individuals with relapsed or refractory MM who had received at least three prior lines of therapy treated with anito-cel showed an overall response rate of 96%, with 74% achieving either a complete response (no detectable M-protein by standard testing) or stringent complete response (complete response plus additional markers of disease clearance). Median time to complete response and best response were 3.2 months and 4.8 months, respectively. Progression free survival (PFS) rates were 82.1% at 12 months, 67.4% at 18 months and 61.7% at 24 months. The overall survival (OS) rates were 94% at 12 months, 88% at 18 months and 83% at 24 months. The median PFS and OS had not been reached at report out.

Safety:
Cytokine release syndrome (CRS) was observed in 86% with 17% experiencing grade 2 or higher reaction. Immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in 8% of those treated, with only one grade 3 case and all others grade 2 or lower. Neutropenia occurred in 71%, anemia in 28% and thrombocytopenia in 26%.

Financial impact:
The anticipated price of anito-cel is unknown but expected to be high, consistent with other CAR T-cell therapies. Current data are limited to individuals with MM who have received at least three prior lines of therapy. However, the ongoing phase 3 iMMagine-3 study is evaluating anito-cel in individuals with one to three prior systemic therapies, which, if successful, could expand the eligible treatment population and increase the overall impact.

Product:
Anitocabtagene autoleucel

Indication:
Multiple myeloma, relapsed or refractory

Estimated FDA approval:
December 2026

Therapeutic class:
B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell therapy

Route of administration:
Intravenous (IV) infusion

FDA designations:
Fast Track; Orphan Drug; Regenerative Medicine Advanced Therapy

Manufacturer:
Gilead Sciences

CarelonRx view:
As relapse occurs often in MM, an additional treatment option is encouraging. While lower observed rates of severe CRS and ICANS may differentiate anito-cel from currently available CAR T-cell therapies, longer-term data are needed to better define its place in therapy. Access, treatment logistics, and total cost of care will likely influence uptake.

Other significant product approvals

Other product approvals expected to reach the market in the next 12 months*

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Molgramostim Savara	Autoimmune pulmonary alveolar proteinosis/oral inhalation	**Addition to class:** would be first FDA-approved treatment for this indication	Third quarter 2026	
Oveporexton Takeda	Narcolepsy type 1/oral	**Addition to class:** novel mechanism of action in narcolepsy (also approved in insomnia)	Third quarter 2026	
DTX 401; pariglasgene brecaparvovec Ultragenyx Pharmaceutical	Glycogen storage disease, type 1a/ intravenous (IV)	**First in class:** would be first FDA-approved treatment for this indication; gene therapy	Third quarter 2026	
Rusfertide Takeda	Polycythemia vera/ subcutaneous (SC)	**First in class:** may be add-on therapy to Jakafi® for this indication	Third quarter 2026	
Apitegromab Scholar Rock	Spinal muscular atrophy (SMA)/IV	**First in class:** muscle-targeted therapy to improve motor function for people living with SMA who are receiving survival motor neuron (SMN)-targeted treatment	September 2026	
Zidesamtinib Nuvalent	Non-small cell lung cancer (NSCLC), ROS1-positive/oral	**Addition to class:** for individuals who have received at least one prior ROS1 tyrosine kinase inhibitor	09/18/2026	
Rebisufligene etisparvovec; UX111 Ultragenyx Pharmaceutical	Mucopolysaccharidosis IIIA/IV	**First in class:** gene therapy; would be first FDA-approved agent for this indication	09/19/2026	

In addition to treatments listed previously, these important drugs and biologics listed in the table at left are scheduled to receive Food and Drug Administration (FDA) approval within the next 12 months.*

Table glossary:

Orphan drug/rare disease; expected to be high cost, but with minimal impact to overall drug/medical spend due to low utilization

Potential to significantly increase overall drug/ medical spend

New entrant into current or future high-spend/ trending category

No significant impact to incremental spend due to replacement of existing competitors based on initial analysis

* As of May 21, 2026

Other product approvals expected to reach the market in the next 12 months* (*continued*)

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Zilganersen Ionis Pharmaceuticals	Alexander disease/ intrathecal	**First in class:** would be first FDA-approved treatment for this indication	09/22/2026	
Tavapadon Cerevel	Parkinson's disease/oral	**First in class:** submission based on data in early disease and as adjunctive to levodopa in individuals experiencing motor fluctuations	09/26/2026	
Lirafugratinib Elevar Therapeutics	Biliary tract cancer/oral	**First in class:** second-line treatment option for individuals with fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement	09/27/2026	
Relutrigine Praxis Precision Medicines	Treatment of SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs)/ oral	**First in class:** would be first FDA-approved treatment for this indication	09/27/2026	
Emcitate® (tiratricol) Egetis Therapeutics	Monocarboxylate transporter 8 deficiency/ oral	**Addition to class:** would be first FDA-approved treatment for this indication	09/28/2026	
Mim8; Denecimig Novo Nordisk	Hemophilia A/SC	**Addition to class:** for individuals with or without inhibitors; potential for once monthly dosing	09/29/2026	
Pivekimab AbbVie	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)/IV	**Addition to class:** would compete with Elzonris®	09/30/2026	

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Daznelimgene lisbac OS Therapies	Osteosarcoma/IV	**First in class:** for prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma	09/30/2026	
Pimicotinib Abbisklo Therapeutics	Pigmented villonodular synovitis (PVNS)/oral	**Addition to class:** would compete with Turalio® and Romvimza™	Between October and November 2026	
CagriSema (cagrilintide/ semaglutide) Novo Nordisk	Chronic weight management in adults with obesity or overweight/SC	**First in class:** combines a novel amylin analogue with an existing glucagon-like peptide-1 (GLP-1) receptor agonist	Fourth quarter 2026	
Pritelivir AiCuris	Herpes simplex virus (HSV) infection/oral	**First in class:** for refractory disease with or without resistance in immunocompromised individuals	Fourth quarter 2026	
Ifinatamab deruxtecan Merck	Small cell lung cancer (SCLC)/IV	**First in class:** for individuals with extensive-stage SCLC with disease progression on or after platinum-based chemotherapy	10/10/2026	
Bepirovirsen GlaxoSmithKline	Hepatitis B treatment/SC	**Addition to class:** potential functional cure; add on therapy	10/26/2026	
Efsitora alfa Eli Lilly	Type 2 diabetes mellitus/ SC	**Addition to class:** long-acting basal insulin analog for once-weekly dosing	10/30/2026	
INO-3107 Inovio Pharmaceuticals	Recurrent respiratory papillomatosis/ intramuscular (IM) injection	**First in class:** would compete with Papzimeos™; more convenient administration	10/30/2026	

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Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Gefurulimab AstraZeneca	Myasthenia gravis/SC	**Addition to class:** once weekly, self-administered injection	Between November and December 2026	
Tegoprazan Sebela Pharmaceuticals	Nonerosive reflux disease (NERD), erosive esophagitis (EE) healing, and EE maintenance/oral	**Addition to class:** would compete with proton pump inhibitors (PPIs) and Voquezna®	11/13/2026	
Ivonescimab Akeso	Non-small cell lung cancer (NSCLC)/IV	**First in class:** novel agent for second-line or later treatment of individuals with epidermal growth factor receptor (EGFR)-mutated locally advanced or metastatic nonsquamous NSCLC	11/14/2026	
Zanzalintinib Exelixis	Colorectal cancer, in combination with Tecentriq®/oral	**Addition to class:** in individuals with metastatic disease who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy	12/03/2026	
Imsidolimab Vanda Pharmaceuticals	Generalized pustular psoriasis (GPP)/IV; SC	**Addition to class:** for both treatment of flares and maintenance therapy	12/12/2026	
Giredestrant Roche	Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated locally advanced or metastatic breast cancer following recurrence or progression on a prior endocrine-based regimen/oral	**Addition to class:** for combination use with everolimus; would be first selective estrogen receptor degrader (SERD) combination approved in the post-cyclin-dependent kinase (CDK)4/6 inhibitor setting	12/18/2026	

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Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Tirabrutinib Gilead Sciences	Primary central nervous system lymphoma/oral	**Addition to class:** would compete with Yescarta® and Rozlytrek® for this indication	12/18/2026	
Imlifidase Sarepta Therapeutics	Desensitization of highly sensitized adults undergoing deceased donor kidney transplantation/IV	**First in class:** would be first FDA-approved treatment for this indication; one-time treatment	12/19/2026	
Lorundrostat Mineralys Therapeutics	Resistant hypertension/ oral	**First in class:** would compete most directly with Tryvio™ and baxdrostat (other pipeline drug in this class for hypertension)	12/22/2026	
Anitocabtagene autoleucel Arcellx	Multiple myeloma/IV	**First in class:** next-generation chimeric antigen receptor (CAR) T-cell therapy	12/23/2026	
Bezuclastinib Cogent Biosciences	Mastocytosis/oral	**Addition to class:** for individuals with nonadvanced systemic disease	12/30/2026	
Daraxonrasib Revolution Medicines	Pancreatic cancer/oral	**First in class:** second-line treatment; targets mutations common in pancreatic cancer	September 2026	
Lorecivivint Biosplice Therapeutics	Osteoarthritis/intra-articular	**First in class:** potential to be disease modifying	01/06/2027	
Serplulimab Shanghai Henlius Biotech	Extensive-stage small cell lung cancer (ES-SCLC) and limited-stage small cell lung cancer (LS-SCLC)/IV	**Addition to class:** would compete with other programmed death-1 (PD-1) inhibitor therapies	01/16/2027	

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Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Ulixacaltamide Praxis Precision Medicines	Essential tremor/oral	**Addition to class:** would compete with propranolol	01/29/2027	
Povorcitinib Incyte	Hidradenitis suppurativa/ oral	**Addition to class:** would be first oral treatment for this indication	February 2027	
Zipalertinib Taiho Pharmaceutical	Locally advanced or metastatic non-small cell lung cancer (NSCLC) for individuals with epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutations whose disease has progressed on or after platinum-based chemotherapy/oral	**First in class:** more selective compared with competitor, Zegfrovy®; potentially more tolerable	02/27/2027	
Neladalkib Nuvalent	Non-small cell lung cancer/oral	**Addition to class:** brain-penetrant, ALK-selective inhibitor; potentially better adverse event profile	04/07/2027	
Varegacestat Immunome	Desmoid tumors/oral	**Addition to class:** would compete with Ogsiveo®	04/29/2027	
Encaleret BridgeBio	Hypoparathyroidism, autosomal dominant hypocalcemia type 1 (ADH1)/oral	**Addition to class:** would be first oral treatment for this indication	05/12/2027	

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The FDA requires all approved biologic products, including reference, biosimilar, and interchangeable products, be evaluated for safety and efficacy to determine whether the benefits outweigh any known potential risks.

Reference biologics undergo several phases of clinical studies to establish safety and effectiveness before they are FDA-approved. Clinical trials begin with early, small-scale, phase 1 studies and move toward late-stage, large scale, phase 3 studies. After the biologic has entered the market, post-marketing monitoring continues to assess the safety, efficacy, and clinical benefit in a larger population.

Biosimilar products are highly similar to their reference product in terms of structure and function and lack clinically meaningful differences in terms of safety and efficacy. Biosimilar products may be approved for all or some of the reference product indications due to patent exclusivity.

Prescriptions for biosimilar products need to be written for the biosimilar by name. Biosimilar products that are granted interchangeability are allowed to be substituted for their reference biologic without the intervention of the prescriber. This is similar to how generic drugs may be substituted for brand name drugs. Unlike reference biologics, biosimilar products are not required to submit evidence to establish safety and efficacy. However, a biosimilar manufacturer must submit clinical trial data that establishes biosimilarity with the reference product.

Biosimilar pipeline update

Currently, 87 biosimilar products are FDA approved in the United States, which represent 21 unique reference biologic products. Recent approvals include Ponlimsi™ (denosumab-adet) in March 2026, Langlara™ (insulin glargine-aldy) in April 2026, Ennumo™ (pegfilgrastim-pccg) and Immgolis™ and Immgolis Intri (golimumab-sldi) in May 2026, and Ranluspec® (ranibizumab-hkdz) in June 2026. Sixty-six of the approved products have been launched.

Biosimilar products awaiting launch and/or approval*

Brand name	Brand manufacturer	Biosimilar name	Biosimilar manufacturer	FDA approval*
Avastin®	Genentech; Roche	Avzivi®	Bio-Thera Solutions; Sandoz	12/06/2023
		FKB238	Centus Biotherapeutics; AstraZeneca; Fujifilm Kyowa Kirin	Pending
		HLX04	Henlius	Pending
Enbrel®	Amgen; Immunex	Erelzi™	Sandoz	08/30/2016
		Eticovo™	Samsung Bioepis	04/25/2019
Entyvio®	Takeda, Millennium Pharmaceuticals	AVT16	Alvotech; Teva; Alvogen	Pending
Eylea®	Regeneron	Ahzantive®	Formycon; Santo Holding; Bioeq; Klinge Pharma	06/28/2024
		Enzeevu™	Sandoz; Hexal	08/09/2024
		Eydenzelt®	Celltrion	10/02/2025
		Opuviz™	Samsung Bioepis; Biogen	05/20/2024
		Yesafili™	Momenta; Mylan; Johnson & Johnson; Biocon; Viatris	05/20/2024
		AVT06	Alvotech; Teva; Alvogen	Pending
		SCD411	Sam Chun Dang Pharm; Fresenius Kabi	Pending
Herceptin®	Roche; Genentech	TX05	Tanvex	Pending
Humalog®	Eli Lilly	GL-LIS	Gan & Lee; Sandoz	Pending
Humalog Pen				Pending
Humalog U-100 KwikPen				Pending
Lantus SoloStar®	Sanofi	Langlara	HEC Pharm; Sunshine Lake Pharma; Lanexa Biologics; Lannett	4/29/2026
		GL-GLA	Gan & Lee; Sandoz	Pending

* As of June 18, 2026. Excludes biosimilars that are FDA approved and have launched.

Biosimilar products awaiting launch and/or approval* (*continued*)

Brand name	Brand manufacturer	Biosimilar name	Biosimilar manufacturer	FDA approval*
Lucentis®	Roche; Genentech	Nufymco	Formycon; Bioeq; Zydus; Polpharma	12/18/2025
		Ranluspec	Lupin	6/2/2026
		Lucamzi	Xbrane; Valorum Biologics; Stada	Pending
Neulasta®	Amgen	Armlupeg™	Lupin	11/28/2025
		Ennumo	Apotex; Accord; Intas	5/7/2026
Neupogen®	Amgen	Filkri®	Apotex; Accord; Intas	01/15/2026
Novolog® (10 mL vial)	Novo Nordisk	GL-ASP	Gan & Lee; Sandoz	Pending
Novolog FlexPen				
Novolog FlexTouch				
Novolog PenFill				
Orencia®	Bristol-Myers Squibb	DRL_AB IV	Dr. Reddy's Laboratories	Pending
Perjeta®	Genentech; Roche	Poherdy®	Henlius; Organon	11/13/2025
		PERT-IJS	Biocon	Pending
Prolia®/Xgeva®	Amgen	Boncresa®/Oziltus®	mAbxience; Insud Pharma; Fresenius Kabi; Amneal	12/19/2025
		Osvyrti®/Jubereq®	Intas; Accord	10/29/2025
		Ponlimsi	Teva	3/27/2026
		Xbryk™	Samsung Bioepis; Samsung Biologics	02/13/2025
		ENZ215-P/ENZ215-X	Enzene; Alkem Labs	Pending
		LY06006/LY01011	Luye Pharma Group; Boan Biotech; Nanjing King-friend Biochemical Pharmaceutical	Pending
Simponi®/Simponi Aria	Johnson & Johnson	Immgolis/Immgolis Intri	Bio-Thera Solutions; Accord; Intas	5/15/2026
		AVT05	Alvotech; Teva; Alvogen	Pending
Xolair®	Roche; Genentech; Novartis	Omlyclo®	Celltrion	03/07/2025
		ADL-018	Kashiv Biosciences; Amneal	Pending
		TEV-45779	Teva	Pending

* As of June 18, 2026. Excludes biosimilars that are FDA approved and have launched

Gene therapies in the pipeline

Gene therapy introduces or edits genetic material to treat disease. We group these drugs into (1) single-use gene therapies that aim to cure inherited conditions and (2) gene-based therapeutics that require repeat dosing. Because prices are disclosed only after FDA approval, forecasting remains difficult, but most forthcoming gene therapies are likely to launch in the $2–4 million range, which is consistent with recent approvals.

The following gene therapies and gene-based therapeutics are scheduled to receive an FDA decision in the next 12 months, or we expect they could file a biologics license application (BLA) with the FDA before the end of 2027.

Gene and gene-based therapies with submitted applications for potential FDA approval*

Gene therapy/ gene-based therapy	Indication/route and frequency	Place in therapy	Estimated approval date
Cretostimogene grenadenorepvec Novartis	Bacillus Calmette-Guérin (BCG) unresponsive, non-muscle invasive bladder cancer (NMIBC)/multiple intravesical doses	Second gene-based therapeutic; will compete with Adstiladrin®. Uses viral vector (adeno-associated virus).	Second half 2026–2027 (initiated rolling BLA)
Isaralgagene civaparvovec Sangamo	Fabry disease/single intravenous (IV) infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	Second half 2026–2027 (initiated rolling BLA)
Marnetegragene autotemcel (marne-cel) Rocket	Leukocyte adhesion deficiency-I/ single IV infusion	First gene therapy for this indication. Uses viral vector (lentivirus).	03/28/2026 (refiled)
Dalnacogene ponparvovec Belief BioMed	Hemophilia B/single IV infusion	Third gene therapy for this indication; will compete with Hemgenix. Uses viral vector (adeno-associated virus).	04/12/2026
Pariglasgene brecaparvovec Ultragenyx	Glycogen storage disease type Ia/ single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	Third quarter 2026
Rebisufligene etisparvovec Ultragenyx	Mucopolysaccharidosis IIIA (Sanfilippo Type A)/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	09/19/2026 (refiled)
Sonpiretigene isteparvovec Nanoscope	Retinitis pigmentosa (RP)/single intravitreal injection	First mutation-agnostic gene therapy for RP. Uses viral vector (adeno-associated virus).	Second half 2026 (initiated rolling BLA)
Lonvoguran ziclumeran (lonvo-z) Intellia	Hereditary angioedema (HAE)/ single IV infusion	First gene therapy for this indication. Uses gene editing, delivered by lipid nanoparticles.	2027 (initiated rolling BLA)

* As of May 21, 2026.

Gene and gene-based therapies of significant interest with potential FDA-submissions in 2026/2027*

Gene therapy/ gene-based therapy	Indication/route and frequency	Place in therapy	Estimated approval date
AAV-AIPL1 MieraGTx	Leber congenital amaurosis 4 (LCA4)/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026
Bidridistrogene xeboparvovec Sarepta	Limb-girdle muscular dystrophy (LGMD) Subtype 2E/R4/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026 (trials on hold)
Botaretigene sparoparvovec Johnson & Johnson	X-linked retinitis pigmentosa (XLRP)/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026
Casgevy (exagamglogene autotemcel; exa-cel) Vertex and CRISPR	Sickle cell disease/single IV infusion	Potential to expand approval to include individuals 5 to 11 years of age; will compete with HCT and chronic RBC transfusions. Uses gene editing.	2026
Giroctocogene fitelparvovec Sangamo	Hemophilia A/single IV infusion	Gene therapy for hemophilia A; will compete with FVIII products and Hemlibra®. Uses viral vector (adeno-associated virus).	2026
SGT-003 Solid Biosciences	Duchenne muscular dystrophy (DMD)/single IV infusion	Competing to be second gene therapy for DMD; will compete with Elevidys. Uses viral vector (adeno-associated virus).	2026
Avalotcagene ontaparvovec Ultragenyx	Ornithine transcarbamylase (OTC) deficiency/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026–2027
RGX-202 Regenxbio	Duchenne muscular dystrophy (DMD)/single IV infusion	Second gene therapy for DMD; will compete with Elevidys. Uses viral vector (adeno-associated virus).	2026–2027
RP-A501 Rocket	Danon disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026–2027
AAV-AQP1 MeiraGTx Holdings	Radiation-induced xerostomia/ single intraparotid injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
AMT-130 UniQure	Huntington's disease/single intracerebral	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
AAV-GAD MeiraGTx	Parkinson's disease/single surgical infusion into the brain	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Aglatimagene besadenovec Candel	Intermediate-to-high-risk localized prostate cancer/multiple intratumoral injections	First localized gene-based viral immunotherapy for this indication; used in combination with an oral anti-herpes drug, such as valacyclovir, to destroy cancer cells. Uses viral vector (adeno-associated virus).	2027

* As of May 21, 2026.

Gene and gene-based therapies of significant interest with potential FDA-submissions in 2026/2027*

Gene therapy/ gene-based therapy	Indication/route and frequency	Place in therapy	Estimated approval date
BBP-812 Aspa	Canavan disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Dabocemagene autoficel Castle Creek Biosciences	Dystrophic epidermolysis bullosa (DEB)/multiple intradermal injections	Third localized gene-based wound therapeutic for this indication; will compete with Vyjuvek and Zevaskyn™. Uses viral vector (lentivirus).	2027
Detalimogene voraplasmid enGene	BCG unresponsive, NMIBC/multiple intravesical instillations	Third gene-based therapeutic for NMIBC; will compete with Adstiladrin and cretostimogene grenadenorepvec, if approved. Uses viral vector (adeno-associated virus).	2027
Elevidys (delandistrogene moxeparvovec-rokl) Sarepta	Duchenne muscular dystrophy (DMD)/single IV infusion	Potential to expand approval to include non-ambulatory individuals and individuals 4 years of age and younger with DMD. Uses viral vector (adeno-associated virus).	2027
IMNN-001 Imunon	Newly diagnosed advanced ovarian, fallopian tube, or peritoneal cancers/multiple intraperitoneal infusions	First gene-based oncolytic immunotherapy for these indications; used in combination with chemotherapy. Uses a DNA plasmid vector enclosed in a nanoparticle delivery system.	2027
KB801 Krystal	Neurotrophic keratitis (NK)/ multiple ophthalmic doses	First gene-based therapeutic for NK. Uses viral vector (herpes simplex virus type 1 (HSV-1)).	2027
KB803 (beremagene geperpavec) Krystal Biotech	Dystrophic epidermolysis bullosa (DEB)/multiple ophthalmic doses	First ophthalmic formulation of Vyjuvek™ to treat ocular complications secondary to DEB. Uses viral vector (herpes simplex virus).	2027
Laruparetigene zovaparvovec Beacon	X-linked retinitis pigmentosa (XLRP)/single subretinal injection	Second gene therapy for this indication; potential to compete with botaretigene sparoparvovec, if its approved. Uses non-viral vector (Dually Derivatized Oligochitosan® (DDX) platform).	2027
LX2006 Lexeo	Friedreich's Ataxia Cardiomyopathy/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
PM-359 Prime Medicine	Chronic granulomatous disease/ single IV infusion	First gene therapy for this indication. Uses gene editing.	2027
OCU400 Ocugen	Retinitis pigmentosa (RP)/single subretinal injection	Potential to be first gene therapy for RP associated with *RHO* mutations; may also get approval for people with any other RP associated mutation with a clinical phenotype of RP. Uses viral vector (adeno-associated virus).	2027
Ristoglogene autogetemcel (risto-cel) Beam Therapeutics	Sickle cell disease (SCD)/single IV infusion	Third gene therapy for this indication; will compete with Casgevy and Lyfgenia. Uses gene editing.	2027

* As of May 21, 2026.

Gene and gene-based therapies of significant interest with potential FDA-submissions in 2026/2027*

Gene therapy/ gene-based therapy	Indication/route and frequency	Place in therapy	Estimated approval date
Rivunatpagene miziparvovec Ultragenyx	Wilson disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Surabgene lomparvovec Regenxbio	Neovascular age-related macular degeneration (wet AMD)/single subretinal and/or suprachoroidal injection	First gene therapy for this indication; will compete with treatments requiring multiple intravitreal injections such as Eylea® and Vabysmo®. Uses viral vector (adeno-associated virus).	2027
Tavokinogene telseplasmid (TAVO) OncoSec Medical	Metastatic melanoma/multiple intratumoral injections	Addition to class; gene-based oncolytic immunotherapy; used in combination with Keytruda®; uses non-viral vector (plasmid DNA).	2027
TG-C Kolon TissueGene	Osteoarthritis of the knee/multiple intraarticular injections	First gene-based therapeutic for this indication; potential to compete with intraarticular steroid injections and knee replacement surgery. Uses viral vector (retrovirus).	2027
TSHA-102 Taysha Gene Therapies	Rett syndrome/single intrathecal infusion	Competing to be the first gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Avigbagene parvec (FLT201) Spur Therapeutics	Gaucher disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
BEAM-302 Beacon Therapeutics	Alpha-1 antitrypsin deficiency (AATD)/single IV infusion	First gene therapy for this indication. Uses gene editing.	2027–2028
KB407 Krystal	Cystic fibrosis (CF)/multiple inhalations via nebulization	First gene-based, mutation-agnostic therapeutic for CF. Uses viral vector (HSV-1).	2027–2028
NGN-401 Neurogene	Rett syndrome/single intracerebroventricular infusion	Competing to be the first gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
OCU410ST Ocugen	Stargardt disease/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
OTL-203 Orchard	Mucopolysaccharidosis I (MPS I; Hurler Syndrome)/ single IV infusion	First gene therapy for this indication. Uses viral vector (lentivirus).	2027–2028
4D-150 4D Molecular Therapeutics	Neovascular age-related macular degeneration (wet AMD)/single intravitreal injection	Competing to be first gene therapy for this indication; could compete with surabgene lomparvovec. Uses viral vector (adeno-associated virus).	2028

* As of May 21, 2026.

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