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DrugInsights

Q1 2026

CarelonRx DrugInsights provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, biosimilars, and indications. We continue to closely monitor the FDA landscape to help provide our audiences with an understanding of the current drug and biologic market.

New molecular entities

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Adquey™ (difamilast)	Phospho-diesterase 4 inhibitor	Eucrisa®, Zoryve®	Treatment of adults and pediatric individuals age 2 and older with mild to moderate atopic dermatitis	Apply twice daily to affected areas	Acrotech Biopharma	Not available
Aqvesme™ (mitapivat)	Pyruvate kinase activator	First therapy approved for alpha-thalassemia	Treatment of anemia in adults with alpha- or beta-thalassemia	100 mg orally twice daily with or without food	Agios	$35,000 per month
Cardamyst™ (etripamil)	Calcium channel blocker	First self-administered therapy	Conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults	Initial dosage: 70 mg administered as two nasal sprays, one in each nostril. If symptoms persist for 10 minutes take a second dose. Do not exceed 140 mg in 24 hours.	Milestone	$1,649 per package of two

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Exdensur (depemokimab-ulaa)	Interleukin-5 (IL-5) antagonist	Cinqair®, Dupixent®, Fasenra®, Nucala, Tezspire®, Xolair®	Add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in individuals age 12 and older	100 mg administered as a subcutaneous injection (SC) once every six months by a healthcare provider	GlaxoSmithKline	$52,000 per year
Myqorzo™ (aficamten)	Cardiac myosin inhibitor	Camzyos®	Treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	5 mg orally once daily	Cytokinetics	$107,000 per year
Nereus™ (tradipitant)	Substance P/ neurokinin-1 (NK-1) receptor antagonist	scopolamine	Prevention of vomiting induced by motion in adults	85 or 170 mg as a single oral dose approximately 60 minutes before an event expected to cause vomiting induced by motion	Vanda	Not available
Nuzolvence® (zoliflodacin)	Spiro-pyrimidine-trione bacterial type II topoisomerase inhibitor	ceftriaxone	Treatment of uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric individuals age 12 and older weighing at least 35 kg	3 g (one packet) administered as a single oral dose	Innoviva	Not available

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Waskyra™ (etuvetidigene autotemcel)	Gene therapy	First therapy approved for this indication	Treatment of individuals age 6 months and older with Wiskott-Aldrich Syndrome (WAS) who have WAS gene mutation for whom hematopoietic stem cell transplantation is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available	One-time intravenous infusion	Fondazione Telethon ETS	$3.25 million per treatment
Yartemlea® (narsoplimab-wuug)	Mannose-binding lectin-associated serine protease MASP-2 inhibitor	First therapy approved for this indication	Treatment of adults and pediatric individuals age 2 and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)	50 kg and higher: 370 mg given as an intravenous (IV) infusion over 30 minutes once weekly. Increase frequency to twice weekly if improvement isinadequate. Less than 50 kg: 4 mg/kg given as an IV infusion over 30 minutes once weekly. Increase frequency to twice weekly if improvement is inadequate.	Omeros Corporation	Not available
Zycubo® (copper histidinate)	Copper replacement product	First agent approved for this indication	Treatment of Menkes disease in pediatric individuals	Less than 1 year old: 1.45 mg twice daily by SC injection (8–12 hours between injections) 1 year old to less than 17 years old: 1.45 mg once daily by SC injection	Sentynl Therapeutics	$1,867 per 2.9 mg single-dose vial

New formulations

Brand (generic)	Description
Daybue® Stix (trofinetide)	Trofinetide powder for oral solution approved for the treatment of Rett syndrome in adult and pediatric individuals age 2 and older.
Fesilty™ (fibrinogen, human-chmt)*	Human fibrinogen intravenous product approved for the treatment of acute bleeding episodes in pediatric and adult individuals with congenital fibrinogen deficiency (CFD) including hypo- or afibrinogenemia.
Lunsumio Velo™ (mosunetuzumab-axgb)*	Subcutaneous formulation of mosunetuzumab for the treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
Orladeyo® (berotralstat)	Oral pellet formulation approved for prophylaxis to prevent attacks of hereditary angioedema (HAE) in pediatric individuals age 2 to less than age 12.
Ozempic® (semaglutide)	Semaglutide 1.5 mg, 4 mg, and 9 mg tablets approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular (CV) events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.
Quiofic™ (folic acid)	Folic acid oral solution approved for the treatment of megaloblastic anemias due to a folic acid deficiency in adult and pediatric individuals.
Rybrevant Faspro™ (amivantamab and hyaluronidase-lpuj)*	Amivantamab subcutaneous formulation approved for the treatment of individuals with non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) mutations across all approved indications for Rybrevant amivantamab-vmjw.
Vybrique™ (sildenafil)	Sildenafil oral film formulation approved for the treatment of erectile dysfunction.
Vykoura™ (leucovorin calcium)*	Leucovorin calcium injection for intravenous or intramuscular use approved for rescue after high-dose methotrexate therapy in adult and pediatric individuals, reducing the toxicity of methotrexate in adult and pediatric individuals with impaired methotrexate elimination or folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose in adult and pediatric individuals, treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric individuals when oral therapy is not feasible, and treatment of individuals with metastatic colorectal cancer in combination with 5-fluorouracil.
Wegovy® (semaglutide)	Semaglutide oral formulation approved to reduce the risk of major adverse CV events, such as CV death, nonfatal myocardial infarction, or nonfatal stroke, in adults with established CV disease and either obesity or overweight and to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.
Yuvezzi™ (carbachol/brimonidine tartrate)	Carbachol and brimonidine tartrate ophthalmic solution approved for the treatment of presbyopia in adults.

* Injectable

New biosimilars

Brand (generic)	Description
Armlupeg™ (pegfilgrastim-unne)*	Neulasta® biosimilar approved to decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. It is also approved to increase survival in individuals acutely exposed to myelosuppressive doses of radiation.
Boncresa® (denosumab-mobz)*	Prolia® biosimilar approved for postmenopausal women with osteoporosis who are at a high risk of fracture, men with osteoporosis who are at a high risk of fracture and need to increase bone mass, men and women with glucocorticoid-induced osteoporosis who are at a high risk of fracture, men receiving androgen deprivation therapy for nonmetastatic prostate cancer who are at a high risk of fracture and need to increase bone mass, and women receiving adjuvant aromatase inhibitor therapy for breast cancer who are at a high risk of fracture and need to increase bone mass.
Filkri® (filgrastim-laha)*	Neupogen® biosimilar approved to: • Decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. • Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of individuals with acute myeloid leukemia (AML). • Reduce the duration of neutropenia and neutropenia-related clinical sequelae, including febrile neutropenia, in individuals with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). • Reduce the incidence and duration of sequelae of severe neutropenia, such as fever, infections, and oropharyngeal ulcers, in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. • Increase survival in individuals acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome).
Nufymco® (ranibizumab-leyk)*	Lucentis® biosimilar approved for neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), and myopic choroidal neovascularization (mCNV).
Oziltus™ (denosumab-mobz)*	Xgeva® biosimilar approved for the prevention of skeletal-related events in individuals with multiple myeloma and in individuals with bone metastases from solid tumors, 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 treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

* Injectable

New indications

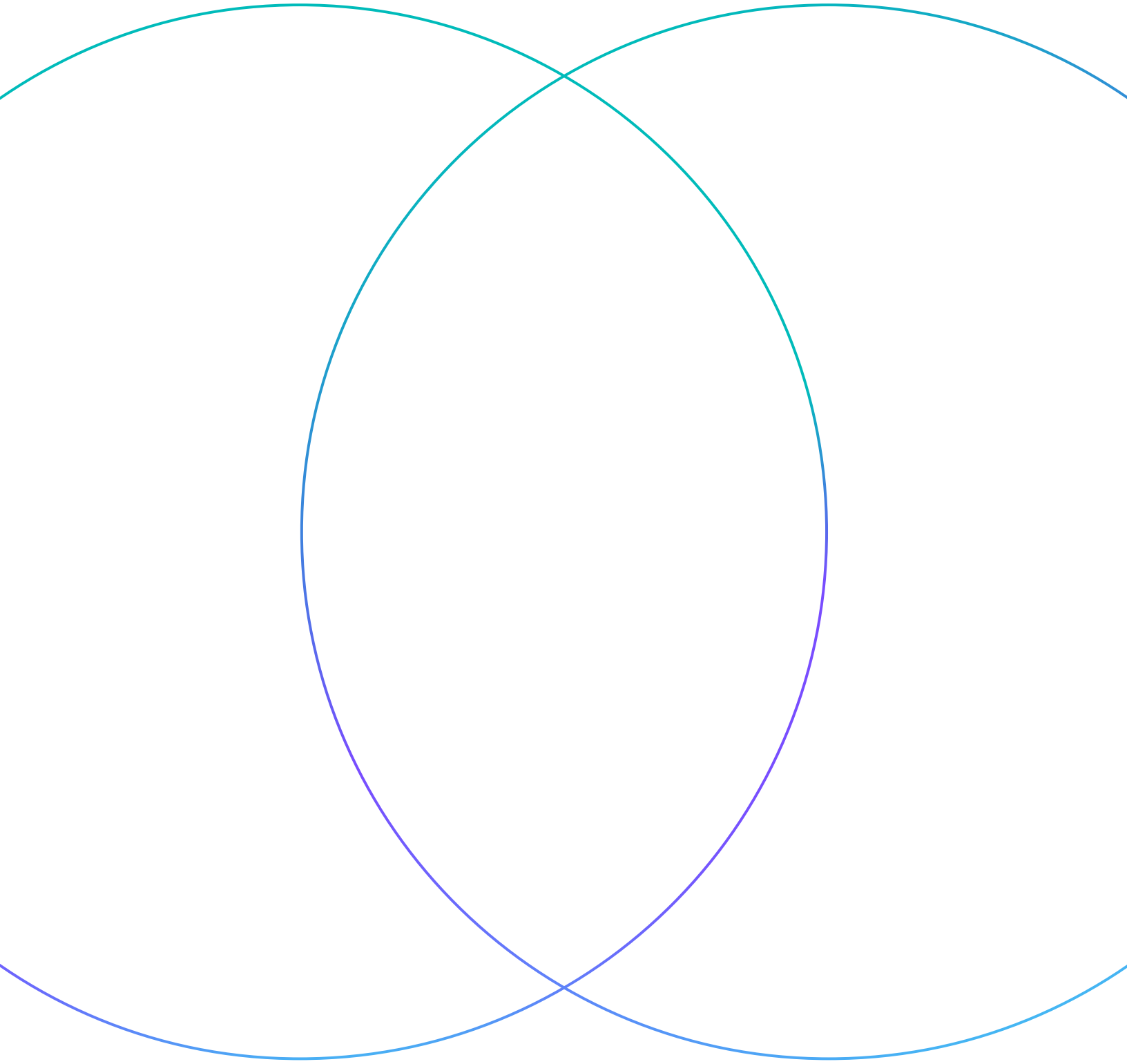
Brand (generic)	Description
Accrufer® (ferric maltol)	Accrufer approved for the treatment of iron deficiency in pediatric individuals age 10 and older.
Addyi® (flibanserin)	Addyi approved for the treatment of hypoactive sexual desire disorder (HSDD) in postmenopausal women age 65 and younger.
Akeega® (niraparib/ abiraterone acetate)	Akeega approved with prednisone for adults with deleterious or suspected deleterious BRCA2-mutated (BRCA2m) metastatic castration-sensitive prostate cancer (mCSPC), as determined by a Food and Drug Administration (FDA)-approved test.
Blujepa (gepotidacin)	Blujepa approved for the treatment of uncomplicated urogenital gonorrhea in adult and pediatric individuals age 12 and older weighing at least 45 kilograms who have limited or no alternative treatment options.
Breyanzi® (lisocabtagene maraleucel)*	Breyanzi approved for adults with relapsed or refractory marginal zone lymphoma (MZL) who have received at least two prior lines of systemic therapy.
Cablivi® (caplacizumab-yhdp)*	Cablivi approved for the treatment of pediatric individuals age 12 and older with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy.
Caldolor® (ibuprofen)*	Caldolor approved for the treatment of postoperative pain.
Cerezyme® (imiglucerase)*	Cerezyme approved for the treatment of type 3 Gaucher disease in adult and pediatric individuals and for expansion of the type 1 Gaucher disease population to pediatric individuals less than 2 years old.
Darzalex Faspro® (daratumumab and hyaluronidase-fihj)*	Darzalex Faspro approved in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).
Jascayd® (nerandomilast)	Jascayd approved for the treatment of progressive pulmonary fibrosis in adults.
Jaypirca® (pirtobrutinib)	Jaypirca approved for the treatment of adults with relapsed or refractory (R/R) chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent Bruton tyrosine kinase (BTK) inhibitor.
Journavx® (suzetrigine)	Journavx approved for the treatment of postoperative pain in adults.
Keytruda® (pembrolizumab)*, Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph)*	Keytruda and Keytruda Qlex approved in combination with paclitaxel, with or without bevacizumab, for adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express programmed death-ligand 1 (PD-L1) (CPS≥1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

* Injectable

New indications, *continued*

Brand (generic)	Description
Leqvio® (inclisiran)*	Leqvio approved as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in pediatric individuals 12 and older with heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH).
Mounjaro® (tirzepatide)*	Mounjaro approved as an adjunct to diet and exercise to improve glycemic control in pediatric individuals age 10 and older with type 2 diabetes mellitus.
Nexplanon® (etonogestrel)	Nexplanon approved for the prevention of pregnancy in women of reproductive potential for up to five years.
Noxafil® (posaconazole)*	Noxafil approved for the expanded treatment of invasive aspergillosis to include individuals age 2 to less than age 13 who weigh 10 kg or greater for Noxafil Injection, individuals age 2 to less than age 13 who weigh greater than 40 kg for Noxafil delayed-release tablets, and the addition of the indication for treatment of invasive aspergillosis in individuals age 2 and older who weigh 10 kg to 40 kg for the Noxafil PowderMix for delayed-release oral suspension.
Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy)*	Opdivo Qvantig approved to expand the current melanoma and unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer indications in product labeling to allow for use in pediatric individuals age 12 and older.
Rapiblyk™ (landiolol)*	Rapiblyk approved for the short-term reduction of ventricular rate in pediatric individuals with supraventricular tachycardia.
Recarbrio® (cilastatin sodium/imipenem/ relebactam)*	Recarbrio approved for the addition of pediatric individuals (birth to less than 18 years old) weighing at least 2 kg to the approved indications for treatment of complicated urinary tract infections (cUTI), including pyelonephritis in individuals who have limited or no alternative treatment options, complicated intra-abdominal infections (cIAI) in individuals who have limited or no alternative treatment options, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs)*	Tecentriq Hybreza approved to expand the current unresectable or metastatic alveolar soft part sarcoma indication (ASPS) in product labeling to allow for use in pediatric individuals age 12 and older who weigh 40 kg or greater.
Uplizna® (inebilizumab-cdon)*	Uplizna approved for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) and anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+).
Vraylar® (cariprazine)	Vraylar approved for inclusion of pediatric individuals ages 13 to 17 for the treatment of schizophrenia and inclusion of pediatric individuals ages 10 to 17 for the acute treatment of manic or mixed episodes associated with bipolar I disorder.
Wakix® (pitolisant)	Wakix approved for the treatment of cataplexy in individuals age 6 and older with narcolepsy.

* Injectable



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