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DrugInsights

Q1 2025

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)
Alhemo® (concizumab-mtci)	Tissue factor pathway inhibitor (TFPI) antagonist	Hympavzi™	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric individuals 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and hemophilia B (congenital factor IX deficiency) with FIX inhibitors	Day 1: Loading dose of 1 mg/kg administered by subcutaneous injection Day 2: Once-daily dose of 0.2 mg/kg until individualization of maintenance dose (per prescribing information) no later than 8 weeks after initiation of treatment	Novo Nordisk	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Alyftrek™ (vanzacaftor/ tezacaftor/ deutivacaftor)	Cystic fibrosis conductance regulator (CFTR) corrector (tezacaftor, vanzacaftor) and CFTR potentiator (deutivacaftor)	Trikafta®	Treatment of cystic fibrosis (CF) in individuals aged 6 years and older who have at least one *F508del* mutation or another responsive mutation in the *CFTR* gene	Weight-based once daily oral dosage with a fat-containing food	Vertex	$370K per year
Bizengri® (zenocutuzumab-zbco)	Bispecific HER2- and HER3-directed antibody	First approved treatment for these populations	Adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) or pancreatic adenocarcinoma harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy	750 mg administered as an intravenous infusion every 2 weeks until disease progression or unacceptable toxicity	Merus N.V.	Not available
Crenessity™ (crinecerfont)	Corticotropin-releasing factor type 1 receptor antagonist	Gluco-corticoids	Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric individuals 4 years of age and older with classic congenital adrenal hyperplasia (CAH)	Adults: 100 mg orally, twice daily with a meal in the morning and evening Pediatric (4 years of age and older): Weight-based dosage orally, twice daily with a meal in the morning and evening	Neurocrine Biosciences	$460K per year
Ctexli™ (chenodiol)	Bile acid	First agent approved for this indication	Treatment of cerebrotendinous xanthomatosis (CTX) in adults	250 mg orally three times daily	Mirum Pharma	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Datroway® (datopotamab deruxtecan-dlnk)	Antibody-drug conjugate (ADC); Trop-2-directed antibody and topoisomerase inhibitor conjugate	Trodelvy®	Treatment of adults with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease	6 mg/kg administered by intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity	Daiichi Sankyo	$4,900 per vial
Ensacove™ (ensartinib)	ALK inhibitor	Alecensa®, Alunbrig®, Lorbrena®	Treatment of adults with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK inhibitor	225 mg orally once daily, with or without food, taken at the same time each day, until disease progression or unacceptable toxicity	Xcovery Holdings	Not available
Gomekli™ (mirdametinib)	Mitogen-activated protein kinase (MEK) inhibitor	Koselugo®	Adult and pediatric individuals 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection	2 mg/m^2 twice daily orally for the first 21 days of each 28-day cycle. The maximum dose is 4 mg twice daily. Continue until disease progression or unacceptable toxicity.	SpringWorks Therapeutics	Average: $22K per month for pediatrics; $30K per month for adults

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Journavx™ (suzetrigine)	Nonopioid analgesic	Opioids	Treatment of moderate to severe acute pain in adults	Recommended starting dose is 100 mg orally. Starting 12 hours after the initial dose, 50 mg doses can be taken every 12 hours. Use has not been studied beyond 14 days.	Vertex	$435 per 14- day supply
Romvimza™ (vimseltinib)	Kinase inhibitor of colony-stimulating factor 1 receptor (CSF1R)	Turalio®	Treatment of adults with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	30 mg orally twice weekly with a minimum of 72 hours between doses	Deciphera	Not available
Tryngolza™ (olezarsen)	Apolipoprotein C-III (APOC3)-directed antisense oligo-nucleotide	First approved treatment for this indication	Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)	Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)	Ionis	$595K per year
Unloxcyt™ (cosibelimab-ipdl)	Programmed death ligand-1 (PD-L1) blocking antibody	Keytruda®, Libtayo®	Treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation	1,200 mg administered by intravenous infusion over 60 minutes every 3 weeks	Checkpoint Therapeutics	Not available

New formulations

Brand (generic)	Description
Brynovin™ (sitagliptin)	Sitagliptin oral solution approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Emblaveo™ (aztreonam/avibactam)*	Aztreonam and avibactam injection for intravenous use approved in combination with metronidazole for individuals 18 years and older who have limited or no alternative options for the treatment of complicated intra-abdominal infections (cIAI), including those caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Enterobacter cloacae complex*, *Citrobacter freundii complex*, and *Serratia marcescens*.
Evrysdi® (risdiplam)	Risdiplam 5 mg tablet formulation approved for the treatment of spinal muscular atrophy (SMA) in individuals 2 years of age and older weighing at least 20 kg.
Onapgo™ (apomorphine hydrochloride)*	Apomorphine hydrochloride subcutaneous infusion device approved for the treatment of motor fluctuations in adults with advanced Parkinson's disease.
Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy)*	Nivolumab subcutaneous injection approved for renal cell carcinoma, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal carcinoma, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
Penmenvy (meningococcal groups A, B, C, W, and Y vaccine)*	Meningococcal vaccine approved for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age.
Symbravo® (meloxicam/rizatriptan)	Meloxicam and rizatriptan oral tablet combination approved for acute migraine treatment with or without aura.
Vimkunya™ (chikungunya vaccine, recombinant)*	Chikungunya vaccine approved for the prevention of disease caused by chikungunya virus in individuals 12 years of age and older.

* Injectable

New biosimilars

Brand (generic)	Description
Avtozma® (tocilizumab-anoh)*	Actemra® biosimilar approved for giant cell arteritis, coronavirus disease 19 (COVID-19), polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and rheumatoid arthritis.
Merilog™ (insulin-aspart-szjj)*	Novolog® biosimilar approved for the improvement of glycemic control in adults and pediatric individuals with diabetes mellitus.
Ospomyv™ (denosumab-dssb)*	Prolia® biosimilar approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and for the treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

* Injectable

New biosimilars, continued

Brand (generic)	Description
Steqeyma® (ustekinumab-stba)*	Stelara® biosimilar approved for the treatment of Crohn's disease, ulcerative colitis, plaque psoriasis, and psoriatic arthritis.
Xbryk™ (denosumab-dssb)*	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 for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Yesintek™ (ustekinumab-kfce)*	Stelara® biosimilar approved for the treatment of Crohn's disease, ulcerative colitis, plaque psoriasis, and psoriatic arthritis.

* Injectable

New indications

Brand (generic)	Description
Adcetris® (brentuximab vedotin)*	Adcetris approved in combination with lenalidomide and a rituximab product for adults with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or chimeric antigen receptor (CAR) T-cell therapy.
Braftovi® (encorafenib)	Braftovi approved with cetuximab and mFOLFOX6 for individuals with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by a Food and Drug Administration (FDA)-approved test.
Calquence® (acalabrutinib)	Calquence approved with bendamustine and rituximab for adults with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
Enhertu® (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for the treatment of adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer that has progressed on one or more endocrine therapies in the metastatic setting.
Imcivree® (setmelanotide)*	Imcivree approved to include children as young as 2 years old with obesity due to Bardet-Biedl syndrome (BBS) or pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency.
Imfinzi® (durvalumab)*	Imfinzi approved for adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

* Injectable

New indications, continued

Brand (generic)	Description
Invokana® (canagliflozin); Invokamet® (canagliflozin/metformin); Invokamet® XR (canagliflozin/metformin extended-release)	Invokana, Invokamet, and Invokamet XR approved as an adjunct to diet and exercise to improve glycemic control in pediatric individuals aged 10 years and older.
Lumakras® (sotorasib)	Lumakras approved for adults with *KRAS G12C*-mutated metastatic colorectal cancer (mCRC), as determined by a Food and Drug Administration (FDA)-approved test, who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Nemluvio® (nemolizumab-ilto)*	Nemluvio approved for the treatment of individuals 12 years and older with moderate-to-severe atopic dermatitis, in combination with topical corticosteroids (TCS) and/or calcineurin inhibitors (TCI) when the disease is not adequately controlled with topical prescription therapies.
Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide)	Odefsey approved label expansion to include pediatric individuals weighing at least 25 kg to less than 35 kg for the treatment of human immunodeficiency virus-1 (HIV-1) infection as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL and pediatric individuals weighing at least 25 to less than 35 kg for the treatment of HIV-1 infection to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies/mL).
Omvoh® (mirikizumab-mrkz)*	Omvoh approved for the treatment of moderate-to-severe Crohn's disease in adults.
Ozempic® (semaglutide)*	Ozempic approved to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.
Spravato® (esketamine)	Spravato approved for use as monotherapy for individuals with treatment-resistant depression (TRD).
Susvimo™ (ranibizumab)*	Susvimo approved for the treatment of diabetic macular edema (DME).
Tevimbra® (tislelizumab-jsgr)*	Tevimbra approved for use in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express programmed death-ligand 1 (PD-L1) ≥1.
Trikafta® (elexacaftor/tezacaftor/ivacaftor)	Trikafta approved for the treatment of people with cystic fibrosis (CF) ages 2 and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene or a mutation that is responsive to Trikafta based on clinical and/or in vitro data. With this approval, 94 additional non-F508del CFTR mutations have been added to the Trikafta label.

*Injectable

New indications, continued

Brand (generic)	Description
Vtama® (tapinarof)	Vtama approved for the treatment of atopic dermatitis (AD) in adults and pediatric individuals 2 years of age and older.
Xromi® (hydroxyurea)	Xromi approved to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric individuals 2 years of age and older with sickle cell anemia with recurrent moderate to severe painful crises.
Zepbound® (tirzepatide)*	Zepbound approved in combination with a reduced-calorie diet and increased physical activity to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

*Injectable

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