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DrugInsights

Q4 2025

CarelonRx DrugInsights provides a quarterly summary of U.S. 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)
Forzinity™ (elamipretide)	Mitochondrial cardiolipin binder	First agent approved for this indication	To improve muscle strength in adult and pediatric individuals with Barth syndrome weighing at least 30 kg	40 mg subcutaneously once daily	Stealth BioTherapeutics	$795,000 per year
Hyrnuo® (sevabertinib)	Kinase inhibitor	Enhertu®, Hernexeos®	Treatment of adults with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD)– activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy	20 mg orally twice daily with food until disease progression or unacceptable toxicity	Bayer	$24,000 per month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Inlexzo™ (gemcitabine)	Nucleoside metabolic inhibitor	Adstiladrin®, Anktiva®, Keytruda®	Treatment of adults with bacillus Calmette-Guérin (BCG)–unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors	225 mg intravesically every 3 weeks for up to 6 months, followed by once every 12 weeks for up to 18 months, or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity	Janssen Biotech	$69,000 per dose
Inluriyo™ (imlunestrant)	Estrogen receptor (ER) antagonist	Orserdu®	Treatment of adults with ER-positive, human epidermal growth factor receptor 2 (HER2)–negative, estrogen-receptor-1 (ESR1)–mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	400 mg once daily until disease progression or unacceptable toxicity	Lilly	$22,500 per 28-day cycle
Jascayd® (nerandomilast)	Phospho-diesterase-4 enzyme inhibitor	Ofev®, pirfenidone	Treatment of idiopathic pulmonary fibrosis (IPF) in adults	18 mg orally twice daily	Boehringer Ingelheim	$16,000 per month
Komzifti™ (ziftomenib)	Menin inhibitor	Revuforj®	Treatment of adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options	600 mg orally once daily until disease progression or unacceptable toxicity. For individuals without confirmed disease progression or unacceptable toxicity, treat for a minimum of 6 months.	Kura Oncology	$48,500 per month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Kygevvi™ (doxecitine/ doxribtimine)	Pyrimidine nucleosides	First agent approved for this indication	Treatment of thymidine kinase 2 deficiency (TK2D) in adults and pediatrics with an age of symptom onset ≤ 12 years	Dosage based on weight. Titrate to the next dosage level based on tolerability after a minimum of 2 weeks at the current dosage level. Administer orally in 3 equally divided doses approximately 6 hours apart.	UCB	Not available
Lynkuet® (elinzanetant)	Neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist	Veozah®	Treatment of moderate to severe vasomotor symptoms due to menopause	120 mg orally once daily	Bayer	$625 per month
Palsonify™ (paltusotine)	Somatostatin receptor 2 agonist	Lanreotide, Mycapssa®, octreotide, Signifor® LAR, Somavert®	Treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option	Starting dose is 40 mg orally once daily. After 2–4 weeks, based on insulin-like growth factor 1 (IGF-1) levels, titrate to 60 mg once daily.	Crinetics	$290,000 per year
Redemplo® (plozasiran)	Apolipoprotein C-III (ApoC-III)–directed small interfering ribonucleic acid (siRNA)	Tryngolza®	Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)	25 mg injected subcutaneously once every 3 months	Arrowhead	$60,000 per year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Rhapsido® (remibrutinib)	Bruton tyrosine kinase (BTK) inhibitor	Dupixent®, Xolair®	Treatment of chronic spontaneous urticaria (CSU) in adults who remain symptomatic despite H1 antihistamine treatment	25 mg orally twice daily	Novartis	$4,520 per month
Voyxact® (sibeprenlimab-szsi)	A proliferation-inducing ligand (APRIL) blocker	Fabhalta®, Filspari®, Tarpeyo®, Vanrafia®	Reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression	400 mg injected subcutaneously once every 4 weeks	Otsuka	Not available
Wayrilz™ (rilzabrutinib)	Bruton tyrosine kinase (BTK) inhibitor	Eltrombopag, Doptelet®, Nplate®, Tavalisse®	For treatment of adults with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to previous treatment	400 mg orally twice daily	Genzyme Corporation	$17,500 per month

New formulations

Brand (generic)	Description
Bondlido® (lidocaine)	Lidocaine 10% topical system approved for the relief of pain associated with postherpetic neuralgia in adults.
Camcevi ETM® (leuprolide mesylate)*	Leuprolide mesylate 21 mg, ready-to-use long-acting injectable (LAI) formulation administered every 3 months, approved as a treatment for advanced prostate cancer.
Clotic® (clotrimazole)	Clotrimazole otic solution approved for the treatment of fungal otitis externa (otomycosis) due to *Aspergillus* species and *Candida* species in individuals 18 years of age and older.
Contepo™ (fosfomycin)*	Fosfomycin intravenous infusion approved for the treatment of individuals 18 years of age and older with complicated urinary tract infections (cUTI), including acute pyelonephritis, caused by susceptible isolates of *Escherichia coli* and *Klebsiella pneumoniae*.
Enbumyst™ (bumetanide)	Bumetanide nasal spray approved for the treatment of edema associated with congestive heart failure (CHF), and hepatic and renal disease, including nephrotic syndrome in adults.
Epioxa™; Epioxa™ HD (riboflavin 5'-phosphate)	Riboflavin 5'-phosphate ophthalmic solution approved for the treatment of keratoconus in adults and pediatric individuals ages 13 years and older.
Escitalopram	Escitalopram 15 mg oral capsules approved for the treatment of major depressive disorder in adults younger than 65 years of age and pediatric individuals 12 years of age and older and for the treatment of generalized anxiety disorder in adults younger than 65 years of age.
Itvisma® (onasemnogene abeparvovec-brve)*	Intrathecally delivered version of Zolgensma® approved for the treatment of spinal muscular atrophy (SMA) in adult and pediatric individuals 2 years of age and older with confirmed mutation in the *survival motor neuron 1 (SMN1)* gene.
Javadin™ (clonidine hydrochloride)	Clonidine hydrochloride oral solution approved for the treatment of hypertension in adults.
Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph)*	Subcutaneous formulation of pembrolizumab approved for adult and pediatric (12 years and older) solid tumor indications that are approved for the intravenous formulation of pembrolizumab.
Lasix® ONYU (furosemide)*	Furosemide injection device for subcutaneous use approved for the treatment of edema in adults with chronic heart failure.
Leqembi® Iqlik™ (lecanemab-irmb)*	Lecanemab-irmb once-weekly subcutaneous injection approved for maintenance dosing to treat Alzheimer's disease in individuals with mild cognitive impairment or mild dementia stage of disease.
Omvoh® (mirikizumab-mrkz)*	Omvoh once-monthly, single-injection maintenance regimen approved for adults with moderately to severely active ulcerative colitis (UC).
Otezla XR™ (apremilast extended-release)	Apremilast extended-release tablet approved for adults with active psoriatic arthritis (PsA) or plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, and oral ulcers associated with Behçet's disease, and for pediatric individuals 6 years of age and older and weighing at least 50 kg with active PsA or moderate to severe PsO who are candidates for phototherapy or systemic therapy.

* Injectable.

New formulations, continued

Brand (generic)	Description
Qivigy® (immune globulin, human-kthm)*	Immune globulin intravenous 10% solution approved for the treatment of adults with primary humoral immunodeficiency (PI).
Subvenite® (lamotrigine)	Lamotrigine oral suspension approved for epilepsy adjunctive therapy in individuals ages 2 years and older, epilepsy monotherapy in individuals ages 16 years and older, and bipolar disorder.
Zolymbus™ (bimatroprost)	Bimatoprost ophthalmic gel approved for the reduction of elevated intraocular pressure in individuals with open-angle glaucoma or ocular hypertension.
Zoryve® (roflumilast)	Roflumilast 0.05% cream approved for the treatment of mild to moderate atopic dermatitis in children 2 to 5 years of age.

* Injectable.

New biosimilars

Brand (generic)	Description
Aukelso™ (denosumab-kyqq)*	Xgeva® biosimilar approved to prevent skeletal-related events in individuals with multiple myeloma and bone metastases from solid tumors. It was also approved to treat adults and skeletally mature adolescents with a giant cell tumor of bone and to treat hypercalcemia of malignancy that is refractory to bisphosphonate therapy.
Bildyos® (denosumab-nxxp)*	Prolia® biosimilar approved to treat 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.
Bilprevda® (denosumab-nxxp)*	Xgeva® biosimilar approved to prevent skeletal-related events in individuals with multiple myeloma and in individuals with bone metastases from solid tumors, to treat 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 to treat hypercalcemia of malignancy refractory to bisphosphonate therapy.
Bosaya™ (denosumab-kyqq)*	Prolia® biosimilar approved for treating postmenopausal women with osteoporosis at high risk for fracture and to increase bone mass in men with osteoporosis at high risk for fracture. It was also approved for people with glucocorticoid-induced osteoporosis and for increasing bone mass in certain individuals receiving hormone ablation therapy for nonmetastatic prostate or breast cancer.

* Injectable.

New biosimilars, continued

Brand (generic)	Description
Enoby™ (denosumab-qbde)*	Prolia® biosimilar approved for the management of osteoporosis in postmenopausal women at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, the management of glucocorticoid-induced osteoporosis in individuals at high risk for fracture, to increase bone mass in men receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer who are at high risk for fracture, and to increase bone mass in women receiving adjuvant aromatase inhibitor therapy for breast cancer who are at high risk for fracture.
Eydenzelt® (aflibercept-boav)*	Eylea® biosimilar approved for the treatment of individuals with neovascular (wet) age-related macular degeneration (wAMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy (DR).
Jubereq® (denosumab-desu)*	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.
Osvyrti® (denosumab-desu)*	Prolia® biosimilar approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, 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, 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.
Poherdy® (pertuzumab-dpzb)*	Perjeta® interchangeable biosimilar approved for use in combination with trastuzumab and docetaxel for adults with human epidermal growth factor receptor 2 (HER2)–positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease and for use in combination with trastuzumab and chemotherapy as: • Neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. • Adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence.
Xtrenbo™ (denosumab-qbde)*	Xgeva® biosimilar approved for the prevention of skeletal-related complications in individuals with bone metastases from solid tumors and individuals with multiple myeloma, 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 the treatment of individuals with hypercalcemia of malignancy that is refractory to bisphosphonate therapy.

* Injectable.

New indications

Brand (generic)	Description
Axtle™ (pemetrexed dipotassium)*	Axtle approved in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of individuals with metastatic non-squamous non-small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
Blenrep (belantamab mafodotin-blmf)*	Blenrep approved in combination with bortezomib and dexamethasone (BVd) for adults with relapsed or refractory multiple myeloma (MM) who have taken at least two prior treatments, including a proteasome inhibitor and an immunomodulatory agent.
Caplyta® (lumateperone)	Caplyta approved as an adjunctive therapy with antidepressants for the treatment of major depressive disorder (MDD) in adults.
Cyltezo® (adalimumab-adbm)*	Cyltezo approved for the treatment of uveitis (UV) in pediatric individuals 2 years of age and older and hidradenitis suppurativa (HS) in adolescent individuals 12 years of age and older.
Darzalex Faspro® (daratumumab and hyaluronidase-fihj)*	Darzalex Faspro approved for adults with high-risk smoldering multiple myeloma (SMM).
Epkinly® (epcoritamab-bysp)*	Epkinly approved with lenalidomide and rituximab for relapsed or refractory follicular lymphoma (FL).
Evkeeza® (evinacumab-dgnb)*	Evkeeza approval expanded to include children ages 1 year and older with homozygous familial hypercholesterolemia (HoFH).
Eylea HD® (aflibercept 8 mg)*	Eylea HD approved for the treatment of individuals with macular edema following retinal vein occlusion (RVO) with up to every-8-week dosing after an initial monthly dosing period. An every-4-week (monthly) dosing option was also approved for some individuals who may benefit from resuming this dosing schedule across approved indications: wet age-related macular degeneration (wAMD), diabetic macular edema (DME), diabetic retinopathy (DR), and RVO.
Gazyva® (obinutuzumab)*	Gazyva approved for the treatment of adults with active lupus nephritis (LN) who are receiving standard therapy, as well as a shorter 90-minute infusion time after the first infusion, for eligible individuals.
Imfinzi® (durvalumab)*	Imfinzi approved in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as perioperative treatment for individuals with resectable, early-stage and locally advanced (Stage II-IVA) gastric and gastroesophageal junction (GEJ) cancers.
Keytruda®; Keytruda Qlex™ (pembrolizumab; pembrolizumab and berahyaluronidase alfa-pmph)*	Keytruda and Keytruda Qlex approved with Padcev® (enfortumab vedotin-ejfv) as neoadjuvant treatment followed by adjuvant treatment after cystectomy for adults with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin.
Koselugo® (selumetinib)	Koselugo approved for pediatric individuals 1 year of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). An oral granule formulation was also approved.
Koselugo® (selumetinib)	Koselugo approved for adults with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

* Injectable.

New indications, continued

Brand (generic)	Description
Libtayo® (cemiplimab-rwlc)*	Libtayo approved for the adjuvant treatment of adults with cutaneous squamous cell carcinoma (CSCC) at high risk of recurrence after surgery and radiation.
Linzess® (linaclotide)	Linzess approved for pediatric individuals 7 years and older with irritable bowel syndrome with constipation (IBS-C).
Opzelura® (ruxolitinib)	Opzelura approved to include treatment of mild to moderate atopic dermatitis in non-immunocompromised children ages 2 years and older.
Repatha® (evolocumab)*	Repatha approved to include use in adults at increased risk for major adverse cardiovascular events (MACE) due to uncontrolled low-density lipoprotein cholesterol (LDL-C) and as a monotherapy in adults and pediatric individuals ages 10 years and older with homozygous familial hypercholesterolemia (HoFH).
Revuforj® (revumenib)	Revuforj approved for relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 (NPM1) mutation in adult and pediatric individuals 1 year and older who have no satisfactory alternative treatment options.
Rybelsus® (semaglutide)	Rybelsus approved for cardiovascular (CV) risk reduction in adults with type 2 diabetes (T2D) who are at high CV risk, whether or not they've had a prior CV event.
Simponi® (golimumab)*	Simponi approved to include treatment of children with moderately to severely active ulcerative colitis (UC) weighing at least 15 kg.
Tezspire® (tezepelumab)*	Tezspire approved as an add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps in adult and pediatric individuals ages 12 years and older.
Thrombate III® (antithrombin III, human)*	Thrombate III approved to include the treatment of pediatric individuals with hereditary antithrombin deficiency (hATd).
Tremfya® (guselkumab)*	Tremfya approved to include the treatment of pediatric individuals 6 years and older weighing at least 40 kg with moderate to severe plaque psoriasis (PsO), who are candidates for systemic therapy or phototherapy, and for the treatment of active psoriatic arthritis (PsA).
Uzedy® (risperidone extended-release)*	Uzedy approved for the maintenance treatment of bipolar I disorder in adults, either as monotherapy or in combination with lithium or valproate.
Vonvendi® (von Willebrand factor, recombinant)*	Vonvendi approved to include routine prophylaxis to reduce the frequency of bleeding episodes in adults with von Willebrand disease (VWD), including those with Type 1 and 2 disease, and on-demand and perioperative management of bleeding in pediatric individuals with VWD.
Vyjuvek® (beremagene geperpavec-svdt)	Vyjuvek approved to include individuals from birth for the treatment of dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Additionally, Vyjuvek may now be applied at home.
Winrevair™ (sotatercept-csrk)*	Winrevair approved to include treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1 pulmonary hypertension) to improve exercise capacity and WHO functional class (FC), and reduce the risk of clinical worsening events, including hospitalization for PAH, lung transplantation, and death. Previously, the indication did not include the components of clinical worsening events.

* Injectable.

New indications, continued

Brand (generic)	Description
Xeljanz® (tofacitinib citrate)	Xeljanz approved for the treatment of active psoriatic arthritis (PsA) in individuals 2 years of age and older who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
Yuflyma® (adalimumab-aaty)*	Yuflyma approved for the treatment of hidradenitis suppurativa (HS) in individuals ages 12 years and older and uveitis (UV) in pediatric individuals ages 2 years and older.
Zepzelca® (lurbinectedin)*	Zepzelca approved in combination with Tecentriq or Tecentriq Hybreza for the maintenance treatment of adults with extensive-stage small-cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza, carboplatin, and etoposide.

* Injectable.

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