carelon Rx

DrugInsights

Q1 2023

CarelonRx *DrugInsights* provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, 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	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Adstiladrin® (nadofaragene firadenovec-vncg)	Gene-based therapy	Keytruda®, Valstar®	Treatment of adults with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors	75 mL administered by intravesical instillation at concentration of 3 x 10^{11} viral particles (vp)/mL, instilled once every 3 months	Ferring	Not available
Brenzavvy™ (bexagliflozin)	Sodium-glucose cotransporter 2 (SGLT2) inhibitor	Farxiga®, Invokana®, Jardiance®	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes	20 mg by mouth once a day	TheracosBio	Not available
Briumvi™ (ublituximab-xiiy)	Anti-CD20 monoclonal antibody	Kesimpta®, Ocrevus®	Treatment of adults with relapsing forms of multiple sclerosis (MS)	Maintenance dose of 450 mg given by intravenous infusion every 24 weeks	TG Therapeutics	$59K each year

New molecular entities (continued)

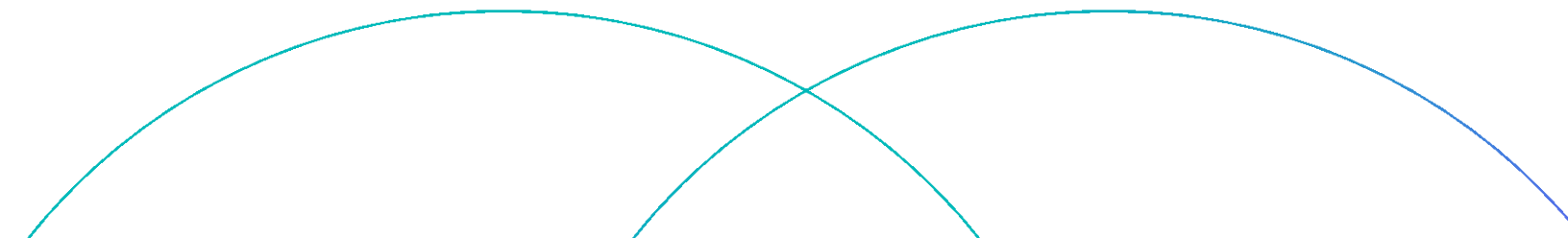
Brand (generic)	Therapeutic class	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Filspari™ (sparsentan)	Endothelin and angiotensin II receptor antagonist	Tarpeyo®	To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression	Initial dose of 200 mg orally once a day. After 14 days, increase to 400 mg once a day, as tolerated.	Travere Therapeutics	$10K each month
Hemgenix® (etranacogene dezaparvovec-drlb)	Gene therapy	First gene therapy approved for hemophilia B	Treatment of adults with hemophilia B (congenital Factor IX deficiency) who: •Currently use Factor IX prophylaxis therapy or •Have current or historical life-threatening hemorrhage or •Have repeated serious spontaneous bleeding	2×10^{13} genome copies (gc) per kg of body weight (or 2 mL/kg body weight) administered as a single infusion after dilution with 0.9% sodium chloride solution	CSL Behring	$3.5 million per person for one-time treatment
Jaypirca™ (pirtobrutinib)	Bruton's tyrosine kinase (BTK) inhibitor	Brukinsa®, Calquence®, Imbruvica®	Treatment of adults with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy	200 mg tablet orally once a day	Eli Lilly	$21K each month

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Jesduvroq (daprodustat)	Hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitor	Erythropoietin stimulating agent (ESA)	Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least 4 months	Recommended dosing is by mouth once a day in the range of 1 to 24 mg	GSK	Not available
Krazati®(adagrasib)	KRAS inhibitor	Lumakras™	Treatment of adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), after at least one prior systemic therapy	600 mg (three 200 mg tablets) by mouth twice a day until disease progression or unacceptable toxicity	Mirati Therapeutics	$20K each month
Lamzede® (velmanase alfa-tycv)	Enzyme (recombinant human lysosomal alpha-mannosidase)	First approval for this indication	Treatment of non-central nervous system manifestations of alpha-mannosidosis (AM) in adults and children	1 mg/kg (actual body weight) once every week by intravenous infusion	Chiesi USA, Inc.	Not available

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Leqembi™ (lecanemab-irmb)	Amyloid beta-directed antibody	Aduhelm®	Treatment of Alzheimer's disease in people with mild cognitive impairment or mild dementia, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.	10 mg/kg that must be diluted and then administered as an intravenous infusion over approximately one hour, once every two weeks	Eisai and Biogen	$21K each year
Lunsumio™ (mosunetuzumab -axgb)	Bispecific T-cell engager	Kymriah®, Yescarta®	Treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	21-day treatment cycles for 8 cycles unless unacceptable toxicity or disease progression	Genentech	$180K each course



New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Orserdu™ (elacestrant)	Selective estrogen receptor degrader (SERD)	Fulvestrant	Treatment of postmenopausal women or adult men with estrogen receptor (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	345 mg tablet by mouth once a day with food	Stemline Therapeutics	$21K each month
Rezlidhia™ (olutasidenib)	IDH1 inhibitor	Tibsovo®	Treatment of adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation	150 mg by mouth twice a day on an empty stomach (1 hour before or 2 hours after a meal) until disease progression or un-acceptable adverse events	Rigel	$32K each month

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitor(s)	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Sunlenca® (lenacapavir)	Human immunodeficiency virus type 1 (HIV-1) capsid inhibitor	Rukobia, Trogarzo®	Treatment of HIV-1 infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug-resistant (MDR) HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations	Subcutaneous (SC) injection (maintenance); oral tablets (treatment initiation) Maintenance: 927 mg by SC injection every 6 months from the date of the last injection (plus or minus 2 weeks)	Gilead	$39K each year
Syfovre™ (pegcetacoplan)	Complement inhibitor	First approval for this indication	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration	15 mg (0.1 mL of 150 mg/mL solution) administered by injection to each affected eye once every 25 to 60 days	Apellis	$2,190 each vial

New formulations

Brand (generic)	Description
Airsupra™ (albuterol/ budesonide)	Albuterol/budesonide oral inhalation approved for the as-needed treatment or prevention of bronchoconstriction and for reduction of the risk of exacerbations in people with asthma age 18 years and older.

Aravalli® (atorvastatin calcium)	Atorvastatin calcium oral suspension approved:
	• To reduce the risk of:
	  ○ Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
	  ○ MI and stroke in adults with type 2 diabetes with multiple risk factors for CHD but without clinically evident CHD
	  ○ Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD
	• As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in:
	  ○ Adults with primary hyperlipidemia
	  ○ Adults and children age 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
	• As an adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and children age 10 years and older with homozygous familial hypercholesterolemia (HoFH)
	• As an adjunct to diet for the treatment of adults with:
	  ○ Primary dysbetalipoproteinemia
	  ○ Hypertriglyceridemia

Austedo® XR (deutetrabenazine extended-release)	Deutetrabenazine extended-release tablets approved for once-a-day treatment of tardive dyskinesia (TD) and chorea associated with Huntington's disease (HD).
Iyuzeh™ (latanoprost)	Latanoprost, preservative-free, 0.005% ophthalmic solution approved for the reduction of elevated intraocular pressure (IOP) in people with open-angle glaucoma or ocular hypertension.
Jylamvo® (methotrexate)	Methotrexate oral solution approved for the treatment of adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen, treatment of adults with mycosis fungoides, treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen, treatment of adults with rheumatoid arthritis, and treatment of adults with severe psoriasis.

New formulations (continued)

Brand (generic)	Description
Nexobrid® (anacaulase-bcdb)	Topical treatment approved for the removal of eschar in adults with deep partial-thickness and/or full-thickness thermal burns.
Olpruva™ (sodium phenylbutyrate)	Sodium phenylbutyrate oral suspension approved for the treatment of people living with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).
Rykindo® (risperidone)*	Risperidone extended-release injectable suspension approved for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.
Tezspire® (Tezepelumab-ekko)*	Tezspire prefilled single-use pen for self-administration approved for the add-on maintenance treatment of people age 12 years and older with severe asthma.

*Injectable

New indications

Brand (generic)	Description
Actemra® (tocilizumab)*	Actemra approved for the treatment of hospitalized adults with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Adacel® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed [Tdap])*	Adacel approved for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months.
Avycaz® (avibactam sodium/ ceftazidime)*	Avycaz approved for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) to include children age 3 months to younger than 18 years.
Brexafemme® (ibrexafungerp)	Brexafemme approved for reduction in incidence of recurrent vulvovaginal candidiasis.
Brukinsa® (zanubrutinib)	Brukinsa approved for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Cibinqo™ (abrocitinib)	Cibinqo approved in children age 12 years and older for the treatment of refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is not advised.

*Injectable

New indications (continued)

Brand (generic)	Description
Enjaymo™ (sutimlimab-jome)*	Enjaymo approved for the treatment of hemolysis in adults with cold agglutinin disease (CAD) to include people with or without a history of transfusions.
Eylea® (aflibercept)*	Eylea approved for the treatment of preterm infants with retinopathy of prematurity (ROP).
Keytruda® (pembrolizumab)*	Keytruda approved for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC).
Odactra® (house dust mite allergen extract)	Odactra approved to include treatment of house dust mite (HDM)-induced allergic rhinitis in children age 12 to 17 years.
Opdivo® (nivolumab)*	Opdivo approved to include children age 12 years and older in combination with Yervoy® for the treatment of unresectable or metastatic melanoma.
Opdivo® (nivolumab)*	Opdivo approved to included children age 12 years and older for the adjuvant treatment of melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

*Injectable

New indications (continued)

Brand (generic)	Description
Pemfexy® (pemetrexed)*	Pemfexy approved in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of people 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.
Revatio® (sildenafil)	Revatio approved for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in children (age 1 to 17 years) to improve exercise ability and, in children too young to perform standard exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.
Rybelsus® (semaglutide)	Rybelsus approved as a first-line treatment option for adults with type 2 diabetes.
Synjardy® (empagliflozin/ metformin) and Synjardy® XR (empagliflozin/metformin extended-release)	Synjardy and Synjardy XR approved to include the reduction of risk for cardiovascular death and hospitalization for heart failure in adults with heart failure.
Takhzyro® (lanadelumab)*	Takhzyro approved in children age 2 years to younger than 12 years for prophylaxis to prevent attacks of hereditary angioedema (HAE).
Trodelvy® (sacituzumab govitecan-hziy)*	Trodelvy approved for people with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
Tukysa® (tucatinib)	Tukysa approved in combination with trastuzumab for RAS wild-type human epidermal growth factor receptor 2 (HER2)-positive unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

*Injectable

New indications (continued)

Brand (generic)	Description
Tymlos® (abaloparatide)*	Tymlos approved as a treatment to increase bone density in men with osteoporosis at high risk of fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or people who have failed or are intolerant to other available osteoporosis therapy.
Udenyca® (pegfilgrastim-cbqv)*	Udenyca approved to increase survival in people acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome).
Vraylar® (cariprazine)	Vraylar approved as adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults.
Wegovy® (semaglutide)*	Wegovy approved as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in children age 12 years and older with an initial body mass index (BMI) at the 95th percentile or greater standardized for age and sex (obesity).

*Injectable

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