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DrugInsights

Q4 2024

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)
Aqneursa™ (leva-cetylleucine	Modified amino acid	Miplyffa™	Treatment of neurological manifestations of Niemann-Pick Disease type C (NPC) in individuals weighing 15 kg or more	Administered orally up to 3 times daily with dosage based on actual body weight	IntraBio	$40K per 28 days
Attruby™ (acoramidis)	Selective stabilizer of transthyretin (TTR)	Vyndamax™, Vyndaqel®	Treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization	712 mg orally twice daily	BridgeBio Pharma	$240K per year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Aucatzyl® (obecabtagene autoleucel)	Chimeric antigen receptor (CAR) T-cell immunotherapy, CD19-directed	Kymriah®, Tecartus®	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)	The total recommended dosage is 410 x 10^6 CAR-positive viable T cells delivered from 3 to 5 infusion bags	Autolus	$525K per year
Cobenfy™ (xanomeline and trospium chloride)	Antipsychotic; combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist	Brand and generic antipsychotics	Treatment of schizophrenia in adults	Starting dosage is 50 mg/20 mg twice daily for at least two days, then increase the dosage to 100 mg/20 mg twice daily for at least five days. Dosage may be increased to 125 mg/30 mg orally twice daily.	Bristol Myers Squibb	$22,500 per year
Ebglyss™ (lebrikizumab-lbkz)	Interleukin-13 (IL-13) antagonist	Adbry®, Dupixent®	Treatment of adult and pediatric people 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	Recommended dosage is 500 mg (two 250 mg injections) at weeks 0 and week 2, followed by 250 mg (one injection) every 2 weeks until week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg every 4 weeks.	Eli Lilly	$3,500 per pen

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Hympavzi™ (marstacimab-hncq)	Tissue factor pathway inhibitor (TFPI) antagonist	Factor products	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatrics 12 years of age and older with: • Hemophilia A without factor VIII inhibitors or • Hemophilia B without factor IX inhibitors.	Recommended dosage is a loading dose of 300 mg (two 150 mg subcutaneous injections given at two different injection sites) followed by 150 mg given every 7 days starting 1 week after the loading dose. Dose may be adjusted to 300 mg weekly. Breakthrough bleeds may be treated with factor VIII or factor IX products; however, no additional Hympavzi may be given.	Pfizer	$795,600 per year
Itovebi™ (inavolisib)	Phosphatidylinositol-3-kinase (PI3K) inhibitor	Piqray®	For use in combination with Ibrance and fulvestrant to treat adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer following recurrence on or after completing adjuvant endocrine therapy	9 mg orally once daily until disease progression or unacceptable toxicity	Genentech	$22,900 per 28-day cycle

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Kebilidi (eladocagene exuparvovec-tneq)	Gene therapy	First treatment approved for this indication	Treatment of adult and pediatric individuals with aromatic L-amino acid decarboxylase (AADC) deficiency	Single-dose intraputaminal infusion (i.e., infusion administered through a surgical procedure into the brain)	PTC Therapeutics	Not available
Miplyffa™ (arimoclomol)	Heat shock protein amplifier	First FDA-approved treatment for this indication	In combination with miglustat for treatment of neurological manifestations of Niemann-Pick disease type C in adult and pediatric people 2 years of age and older	Orally, in combination with miglustat, for individuals with body weight of: • 8 kg to 15 kg = 47 mg three times a day • > 15 kg to 30 kg = 62 mg three times a day • > 30 kg to 55 kg = 93 mg three times a day • > 55 kg = 124 mg three times a day	Zevra Therapeutics	$85K per month (average)
Orlynvah™ (sulopenem etzadroxil and probenecid)	Penem antibacterial (sulopenem) and renal tubular transport inhibitor (probenecid)	Existing oral anti-infectives	Treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options	One tablet orally twice daily for 5 days	Iterum Therapeutics	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Revuforj® (revumenib)	Menin inhibitor	First treatment approved for KMT2A-mutated acute leukemia	Relapsed or refractory acute leukemia lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric individuals aged 1 year and older	Recommended dosage taken orally twice daily fasted or with a low-fat meal. Dosage depends on weight.	Syndax	$475K per year
Vyloy™ (zolbetuximab-clzb)	Claudin 18.2 (CLDN18.2)-directed cytolytic antibody	First agent approved for this specific population	In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive	Recommended first dose is 800 mg/m^2 intravenous infusion (IV) followed by 600 mg/m^2 IV every 3 weeks or 400 mg/m^2 IV every 2 weeks	Astellas Pharma	$1600 per 100 mg vial
Ziihera® (zanidatamab-hrii)	Bispecific HER2-directed antibody	Enhertu®	Treatment of adults with previously treated, unresectable or metastatic HER2-positive biliary tract cancer	20 mg/kg given as an intravenous infusion once every 2 weeks	Jazz	Not available

New formulations

Brand (generic)	Description
Boruzu™ (bortezomib)*	Bortezomib ready-to-use subcutaneous formulation approved for the treatment of adults with multiple myeloma and for the treatment of adults with mantle cell lymphoma.
Bynfezia Pen™ (octreotide acetate)*	Octreotide acetate subcutaneous injection approved for acromegaly, carcinoid tumors, and vasoactive intestinal peptide tumors.
Danziten (nilotinib tartrate)	Nilotinib tablets approved for the treatment of adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Also approved for the treatment of adults with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) resistant or intolerant to prior therapy that included imatinib.
Emrosi (minocycline hydrochloride)	Minocycline hydrochloride extended-release capsules approved for the treatment of inflammatory lesions (papules and pustules) of rosacea in adults.
Imkeldi (imatinib)	Imatinib oral solution approved to treat chronic myeloid leukemia, acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, and gastrointestinal stromal tumors as well as aggressive systematic mastocytosis, hypereosinophilic syndrome, chronic eosinophilic leukemia, and dermatofibrosarcoma protuberans.
Ocrevus Zunovo™ (ocrelizumab & hyaluronidase-ocsq)*	Ocrelizumab subcutaneous injection formulation approved for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS).
Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs)*	Atezolizumab subcutaneous injection formulation approved for all the adult indications as the intravenous formulation including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS).
Vyalev™ (foscarbidopa/ foslevodopa)*	Foscarbidopa and foslevodopa injection for subcutaneous use approved for the treatment of motor fluctuations in adults with advanced Parkinson's disease.

*Injectable

New biosimilars

Brand (generic)	Description
Imuldosa™ (ustekinumab-srlf)*	Biosimilar for Stelara® approved for the treatment of Crohn's disease, ulcerative colitis, moderate-to-severe plaque psoriasis, and active psoriatic arthritis.
Otulfi™ (ustekinumab-aauz)*	Biosimilar for Stelara approved for the treatment of Crohn's disease, ulcerative colitis, moderate-to-severe plaque psoriasis, and active psoriatic arthritis.
Pavblu™ (aflibercept-ayah)*	Pavblu, an Eylea biosimilar, was approved for the treatment of individuals with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy (DR).

New indications

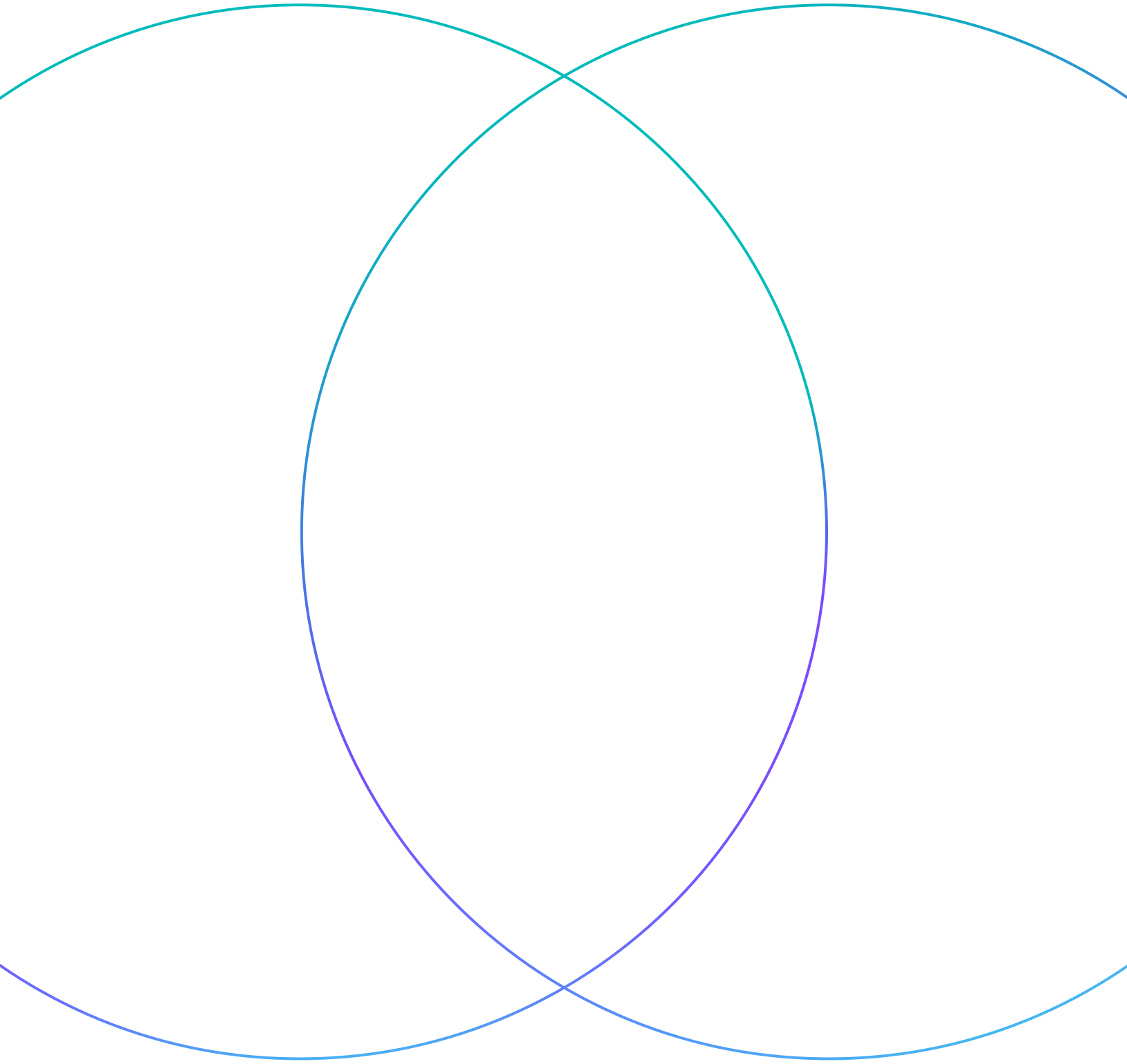
Brand (generic)	Description
Abrysvo® (respiratory syncytial virus vaccine)*	Abrysvo approved to include active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.
ACAM2000™ (smallpox and mpox vaccine, live)*	ACAM2000 approved to include prevention of mpox disease in individuals determined to be at high risk for mpox infection.
Bimzelx® (bimekizumab-bkzx)*	Bimzelx approved for adults with active psoriatic arthritis (PsA), active nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and active ankylosing spondylitis (AS).
Bimzelx® (bimekizumab-bkzx)*	Bimzelx approved to treat active moderate-to-severe hidradenitis suppurativa (HS) in adults responding inadequately to conventional systemic therapy.
Cimzia® (certolizumab pegol)*	Cimzia approved for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) for individuals 2 years of age and older.
Dupixent® (dupilumab)*	Dupixent approved to include add-on maintenance treatment of adolescents aged 12 to 17 years with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
Dupixent® (dupilumab)*	Dupixent approved as an add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
Fasenra® (benralizumab)*	Fasenra approved to treat adults with eosinophilic granulomatosis with polyangiitis (EGPA).
FluMist® (influenza vaccine live)	FluMist intranasal influenza vaccine approved for self- or caregiver-administration for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age.
Jylamvo® (methotrexate)	Jylamvo approved for the treatment of pediatric individuals with polyarticular juvenile idiopathic arthritis (pJIA) and for the treatment of pediatric individuals with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen.

*Injectable

New indications, continued

Brand (generic)	Description
Keytruda® (pembrolizumab)*	Keytruda approved with pemetrexed and platinum chemotherapy as first-line treatment of unresectable advanced or metastatic malignant pleural mesothelioma (MPM).
Kisqali® (ribociclib)	Kisqali approved with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. The Food and Drug Administration (FDA) also approved the Kisqali Femara Co-Pack (ribociclib and letrozole) for the same indication.
Lanreotide acetate*	Lanreotide acetate subcutaneous injection approved for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Lumryz™ (sodium oxybate)	Lumryz approved to include treatment of cataplexy or excessive daytime sleepiness (EDS) in adults 7 years of age and older with narcolepsy.
Opdivo® (nivolumab)*	Opdivo approved with platinum-doublet chemotherapy as neoadjuvant treatment, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
Prevymis® (letermovir)*	Prevymis approved to expand use to include pediatric hematopoietic stem cell transplant recipients 6 months of age and older and weighing at least 6 kg and pediatric kidney transplant recipients 12 years of age and older and weighing at least 40 kg. An oral pellet formulation was also approved.
Rybrevant® (amivantamab-vmjw)*	Rybrevant approved with carboplatin and pemetrexed for adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor.
Sarclisa® (isatuximab-irfc)*	Sarclisa approved for use with bortezomib, lenalidomide, and dexamethasone for adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT).
Scemblix® (asciminib)	Scemblix approved for adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
Selarsdi™ (ustekinumab-aekn)*	Selarsdi approved for the treatment of moderately-to-severely active Crohn's disease and ulcerative colitis.
Tagrisso® (osimertinib)	Tagrisso approved for adults with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by a Food and Drug Administration (FDA)-approved test.
Tremfya® (guselkumab)*	Tremfya approved to treat moderate-to-severe active ulcerative colitis (UC) in adults.

*Injectable



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