carelon Rx

DrugInsights

Q3 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)
Iqirvo® (elafibranor)	Dual peroxisome proliferator-activated receptor alpha/delta (PPAR α,δ) agonist	Livdelzi®, Ocaliva®	Treatment of adults with primary biliary cholangitis (PBC) either in combination with ursodiol with an inadequate response to ursodiol, or as monotherapy in those unable to tolerate it	80 mg orally once daily with or without food	Ipsen	$11,500 per month
Kisunla™ (donanemab-azbt)	Amyloid beta-directed antibody	Leqembi™	Alzheimer's disease, mild cognitive impairment or mild dementia stage of disease	Administered as an intravenous (IV) infusion over 30 minutes at a dose of 700 mg (doses 1-3) every four weeks, then 1400 mg every four weeks	Eli Lilly	$32K per year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Lazcluze™ (lazertinib)	Kinase inhibitor	Rybrevant®, Tagrisso®	First-line treatment of 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, as detected by a Food and Drug Administered (FDA)-approved test, in combination with Rybrevant	Recommended dosage is 240 mg orally daily with or without food, given in combination with Rybrevant, until disease progression or unacceptable toxicity	Janssen	Not available
Leqselvi™ (deuruxolitinib)	Janus kinase (JAK) inhibitor	Litfulo™, Olumiant®	Treatment of adults with severe alopecia areata	8 mg orally twice daily	Sun Pharma	Not available
Livdelzi® (seladelpar)	Peroxisome proliferator-activated receptor (PPAR)-delta (δ) agonist	Iqirvo®, Ocaliva®	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA; ursodiol) in adults who have an inadequate response to UDCA, or as monotherapy in individuals unable to tolerate UDCA	10 mg orally once daily	Gilead	$12,600 per month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Nemluvio® (nemolizumab-ilto)	Interleukin-31 receptor antagonist	Dupixent®	Treatment of adults with prurigo nodularis (PN)	Initial loading dose is 60 mg (two 30 mg injections) followed by either 30 mg (one injection for people weighing less than 90kg) or 60 mg (two separate 30 mg injections for people weighing 90kg or more) given every 4 weeks	Galderma	$4,240 per injection
Niktimvo™ (axatilimab-csfr)	Colony stimulating factor-1 receptor (CSF-1R)-blocking antibody	Rezurock®	Treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric individuals weighing at least 40 kg	Recommended dose is 0.3 mg/kg (maximum 35 mg) administered as an intravenous infusion every 2 weeks in adult and pediatric individuals weighing 40 kg and above	Incyte Corporation	Not available
Ohtuvayre™ (ensifentrine)	Phospho-diesterase 3 (PDE3) inhibitor and phosphor-diesterase 4 (PDE4) inhibitor	Inhaled cortico-steroids (ICSs), long-acting beta-agonists (LABAs) and long-acting muscarinic antagonists (LAMAs)	Maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults	3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer	Verona Pharma	$3K per month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Piasky (crovalimab-akkz)	Complement C5 inhibitor	Empaveli®, Fabhalta®, Soliris®, Ultomiris®, Voydeya™	Treatment of adult and pediatric individuals 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg	Administer loading dose by intravenous infusion, followed by 4 additional loading doses by subcutaneous (SC) injection. Then administer a maintenance dose every 4 weeks by SC injection. Dosages are based on body weight.	Roche	Not available
Rytelo™ (imetelstat)	Oligonucleotide telomerase inhibitor	Reblozyl®	Treatment of adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell (RBC) units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA)	7.1 mg/kg administered by intravenous infusion over 2 hours every 4 weeks	Geron Corporation	$9,884 for 188 mg vial; $2,471 for 47 mg vial
Sofdra™ (sofpironium gel)	Anticholinergic	Qbrexza®	Treatment of primary axillary hyperhidrosis in adults and pediatric individuals 9 years of age and older	Apply 1 pump topically per underarm once a day at bedtime	Botanix	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Tecelra® (afamitresgene autoleucel)	Melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy	First engineered therapy approved by the FDA to target solid tumors	Treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are Human Leukocyte Antigen (HLA)-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 as determined by FDA-approved or cleared companion diagnostic devices	Recommended dose is between 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T cell receptor (TCR) positive T cells administered as a single intravenous infusion	Adaptimmune	$727K for one-time treatment
Voranigo® (vorasidenib)	Isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor	First FDA-approved treatment approved for this type of glioma	Treatment of adults and pediatric individuals 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection	Adults and adolescents 12 years and older weighing 40 kg or more: 40 mg orally once daily until disease progression or unacceptable toxicity Individuals 12 years and older weighing less than 40 kg: 20 mg once daily	Servier	$480K per year
Yorvipath® (palopeg-teriparatide)	Parathyroid hormone analog (PTH(1-34))	Natpara® (will no longer be available after 2024)	Treatment of hypoparathyroidism in adults	Starting dose is 18 mcg given by subcutaneous injection once daily. Maintenance dosing ranges from 6 to 30 mcg once daily.	Ascendis Pharma	Not available

New formulations

Brand (generic)	Description
Adbry® (tralokinumab-ldrm)*	Adbry single-dose autoinjector for self-administration approved for the treatment of adults with moderate-to-severe atopic dermatitis.
Capvaxive™ (pneumococcal 21-valent conjugate vaccine)*	Pneumococcal 21-valent conjugate vaccine approved for: • active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. • active immunization for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
Chewtadzy (tadalafil)	Tadalafil chewable tablets approved for the treatment of erectile dysfunction (ED), benign prostatic hyperplasia (BPH), and ED plus BPH.
Crexont® (carbidopa/levodopa)	Carbidopa and levodopa extended-release capsules approved for the treatment of Parkinson's disease (PD).
Erzofri® (paliperidone palmitate extended-release)*	Paliperidone palmitate extended-release injectable suspension for intramuscular use approved for the treatment of schizophrenia in adults.
Femlyv™ (norethindrone acetate/ethinyl estradiol)	Norethindrone acetate and ethinyl estradiol orally disintegrating tablets approved for the prevention of pregnancy.
Lymphir™ (denileukin diftitox-cxdl)*	Denileukin diftitox injection for intravenous use approved for the treatment of relapsed or refractory cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy.
mResvia® (respiratory syncytial virus vaccine)*	Respiratory syncytial virus vaccine intramuscular injection approved for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
Neffy® (epinephrine)	Epinephrine nasal spray approved for the emergency treatment of allergic reactions (Type I), including those that are life-threatening (anaphylaxis), in adult and pediatric individuals who weigh at least 30 kilograms (about 66 pounds).
Onyda™ XR (clonidine hydrochloride extended-release suspension)	Clonidine hydrochloride extended-release suspension approved for the treatment of attention-deficit/hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medication.
Tepylute (thiotepa)*	Thiotepa injection approved for the treatment of adenocarcinoma of the breast or ovary.
Tezruly™ (terazosin)	Terazosin oral solution approved for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) and the treatment of hypertension alone or with other antihypertensive agents.
Vabysmo™ (faricimab-svoa)*	Faricimab 6.0 mg single-dose prefilled syringe approved for use in the treatment of neovascular or wet age-related macular degeneration (nAMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO).

*Injectable

New formulations, continued

Brand (generic)	Description
Vigafyde™ (vigabatrin)	Vigabatrin oral solution approved as monotherapy for the treatment of pediatric individuals 1 month to 2 years of age with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss.
Yimmugo (immune globulin human-dira)*	Immune globulin approved for the treatment of individuals 2 years of age and older with primary humoral immunodeficiency (PI).
Zituvimet™ XR (sitagliptin/metformin hydrochloride extended-release)	Sitagliptin and metformin hydrochloride extended-release tablets approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Zunveyl® (benzgalantamine)	Zunveyl approved to treat mild-to-moderate dementia associated with Alzheimer's disease (AD) in adults.
Zurnai™ (nalmefene hydrochloride)*	Nalmefene hydrocholoride auto-injector approved for the emergency treatment of known or suspected opioid overdose in adults and pediatric individuals 12 years of age and older.

*Injectable

New biosimilars

Brand (generic)	Description
Ahzantive® (aflibercept-mrbb)*	Eylea® biosimilar 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).
Bkemv™ (eculizumab-aeeb)*	The first interchangeable biosimilar to Soliris® approved for the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and the treatment of individuals with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
Enzeevu™ (aflibercept-abzv)*	Eylea biosimilar approved to improve and maintain visual acuity in individuals with neovascular age-related macular degeneration (nAMD).
Epysqli® (eculizumab-aagh)*	Soliris® biosimilar approved for the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and for the treatment of individuals with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy.
Nypozi™ (filgrastim-txid)*	Neupogen® biosimilar approved for all existing Neupogen FDA-approved indications.
Pyzchiva® (ustekinumab-ttwe)*	Stelara® biosimilar approved for the treatment of moderate-to-severe plaque psoriasis in adult and pediatric individuals 6 years of age and older who are candidates for phototherapy or systemic therapy, active psoriatic arthritis in adult and pediatric individuals 6 years of age and older, and moderately-to-severely active Crohn's disease or ulcerative colitis in adults.

*Injectable

New indications

Brand (generic)	Description
Arexvy (adjuvanted respiratory syncytial virus vaccine)*	Arexvy approved for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) to include those aged 50-59 years who are considered to be at high risk of RSV infection.
Augtyro™ (repotrectinib)	Augtyro approved for adult and pediatric individuals 12 years and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy.
Blincyto® (blinatumomab)*	Blincyto approved for adult and pediatric individuals one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (Ph-negative BCP ALL) in the consolidation phase of multiphase chemotherapy.
Breyanzi® (lisocabtagene maraleucel)*	Breyanzi approved to treat adults with relapsed or refractory (R/R) mantle cell lymphoma (MCL) who were previously administered at least two lines of systemic therapy that included a Bruton tyrosine kinase (BTK) inhibitor.
Brineura® (cerliponase alfa)*	Brineura approval expanded to slow the loss of ambulation in children of all ages with neuronal ceroid lipofuscinosis type 2 (CLN2 disease), also known as tripeptidyl peptidase 1 (TPP1) deficiency.
Darzalex Faspro® (daratumumab and hyaluronidase-fihj)*	Darzalex Faspro approved in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in individuals with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).
Elevidys® (delandistrogene moxeparvovec-rokl)*	Elevidys approval expanded for the treatment of Duchenne muscular dystrophy (DMD) in ambulatory and non-ambulatory individuals 4 years of age and older with DMD with a confirmed mutation in the DMD gene.
Epkinly® (epcoritamab-bysp)*	Epkinly approved for adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
Fabhalta® (iptacopan)	Fabhalta approved for the reduction of proteinuria in primary IgA nephropathy (IgAN).
Farxiga® (dapagliflozin)	Farxiga approved for the treatment of pediatric individuals aged 10 years and above with type-2 diabetes (T2D).
Furoscix® (furosemide)*	Furoscix approval expanded to include treatment of congestion due to fluid overload in adults with chronic heart failure (CHF), regardless of New York Heart Association (NYHA) functional class.
Imfinzi® (durvalumab)*	Imfinzi approved with platinum-containing chemotherapy as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment after surgery 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.
Imfinzi® (durvalumab)*	Imfinzi approved with carboplatin plus paclitaxel followed by single-agent durvalumab for adults with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

*Injectable

New indications, continued

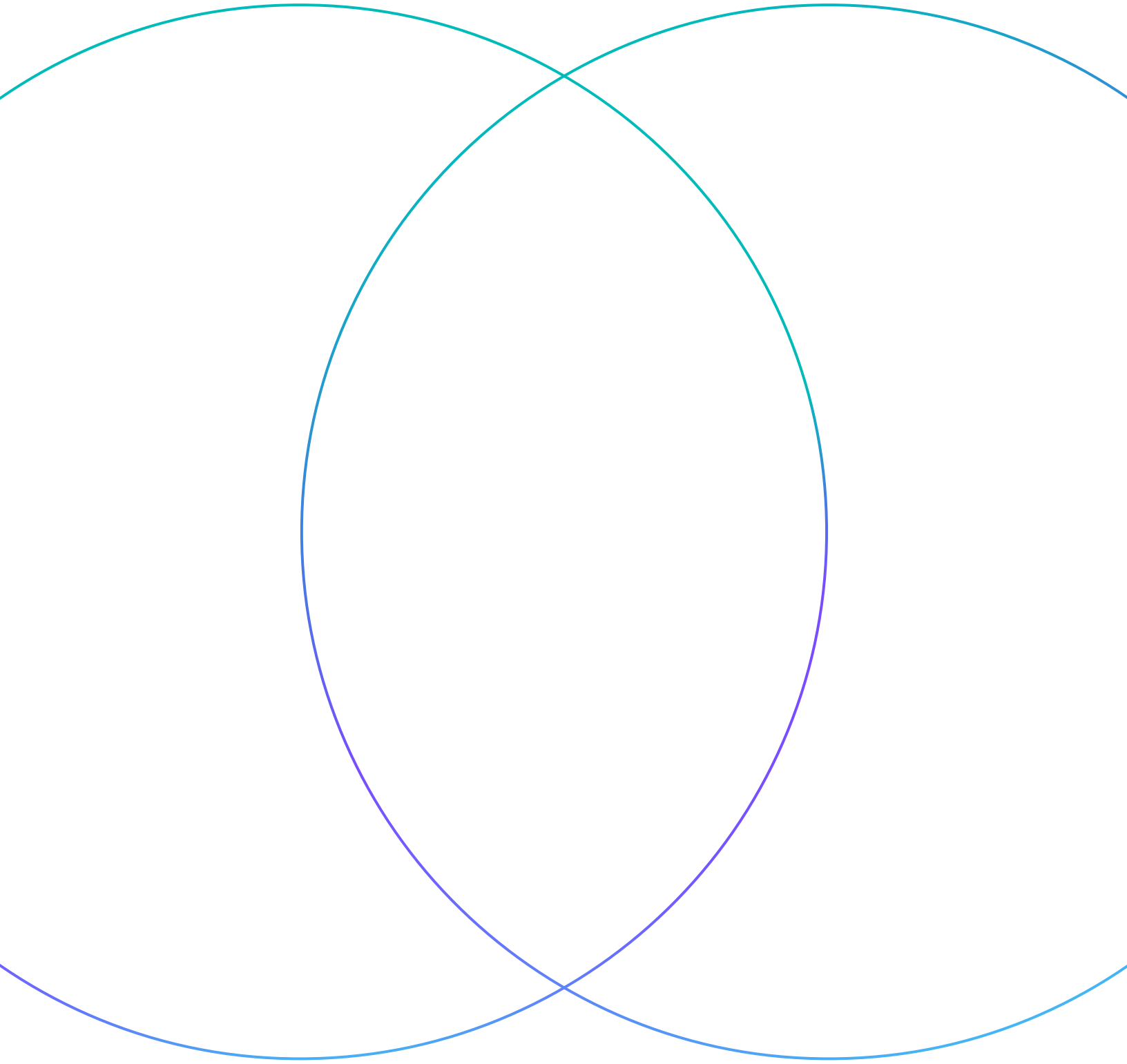
Brand (generic)	Description
Jemperli (dostarlimab-gxly)*	Jemperli approved with carboplatin and paclitaxel, followed by single-agent Jemperli, for adults with primary advanced or recurrent endometrial cancer (EC).
Kevzara® (sarilumab)*	Kevzara approved for the treatment of individuals weighing 63 kg or more with active polyarticular juvenile idiopathic arthritis (pJIA).
Keytruda® (pembrolizumab)*	Keytruda approved with carboplatin and paclitaxel, followed by single-agent pembrolizumab, for adults with primary advanced or recurrent endometrial carcinoma.
Krazati® (adagrasib)	Krazati plus cetuximab approved for adults with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Livmarli® (maralixibat)	Livmarli approval expanded to include the treatment of cholestatic pruritus in individuals 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). A 19 mg/mL high concentration oral solution was also approved.
Motpoly XR™ (lacosamide extended-release)	Motpoly XR approved for the treatment of primary generalized tonic-clonic seizures in adults and in pediatric individuals weighing at least 50 kg.
NexoBrid® (anacaulase-bcdb)	NexoBrid approved for eschar removal in pediatric individuals with deep partial-thickness and/or full-thickness thermal burns.
Palforzia® (peanut allergen powder-dnfp)	Palforzia approved to include initiation of treatment, up-dosing and maintenance in individuals ages 1 through 3 years with a confirmed diagnosis of peanut allergy to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts.
Protonix® I.V. (pantoprazole sodium)*	Protonix I.V. approved for the treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 7 days in pediatric individuals 3 months and older.
Retevmo™ (selpercatinib)	Retevmo approved for pediatric individuals two years of age and older with the following: • advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy; • advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate); and • locally advanced or metastatic solid tumors with a RET gene fusion, as detected by an FDA-approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
Skyrizi® (risankizumab-rzaa)*	Skyrizi approved for the treatment of moderately-to-severely active ulcerative colitis in adults.
Tofidence™ (tocilizumab-bavi)*	Tofidence approved for adults with giant cell arteritis (GCA) and hospitalized adults with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

*Injectable

New indications, continued

Brand (generic)	Description
Velphoro® (ferric oxyhydroxide)	Velphoro approved for the control of serum phosphorus levels in adult and pediatric individuals 9 years of age and older with chronic kidney disease on dialysis.
Voquezna® (vonoprazan)	Voquezna approved for the relief of heartburn associated with nonerosive gastroesophageal reflux disease (GERD) in adults.
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)*	Vyvgart Hytrulo approved for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP).
Wakix® (pitolisant)	Wakix approved for the treatment of excessive daytime sleepiness (EDS) in pediatric individuals 6 years of age and older with narcolepsy.
Xembify® (immune globulin subcutaneous human-klhw)*	Xembify approved to include biweekly dosing and use in treatment-naive individuals for primary immunodeficiency.
Xeomin® (incobotulinumtoxinA)*	Xeomin approved for the temporary improvement of the appearance of upper facial lines in adults.
Xigduo® XR (dapagliflozin/ metformin hydrochloride)	Xigduo XR approved for the treatment of pediatric individuals aged 10 years and above with type-2 diabetes (T2D).
Zoryve® (roflumilast cream)	Zoryve approved for the treatment of mild to moderate atopic dermatitis in adult and pediatric individuals 6 years of age and older.

*Injectable



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