DrugInsights

Q4 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	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Adzynma™ (ADAMTS13, recombinant-krhn)	Enzyme replacement therapy	First therapy approved for this indication	Prophylactic or on-demand enzyme replacement therapy in adult and children with congenital thrombotic thrombocytopenic purpura (cTTP)	For prophylactic therapy, 40 IU/kg intravenous infusion once every other week. Some people may require once weekly dosing. For on-demand therapy, 40 IU/kg IV on day 1, 20 IU/kg on day 2, and 15 IU/kg on day 3 and beyond until 2 days after event is resolved.	Takeda	Not available
Agamree® (vamorolone)	Corticosteroid	Emflaza®	Treatment of Duchenne muscular dystrophy (DMD) in children age 2 years and older	Recommended dosage is 6 mg/kg by mouth once a day preferably with a meal, up to a maximum daily dosage of 300 mg for people weighing more than 50 kg	Santhera	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Aphexda™ (motixafortide)	Hematopoietic stem cell mobilizer; C-X-C Motif Chemokine Receptor 4 (CXCR4) inhibitor	plerixafor	Mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in people with multiple myeloma in combination with filgrastim (granulocyte-colony stimulating factor [G-CSF])	Following completion of four once-daily doses of filgrastim injection, give Aphexda 1.25 mg/kg 10 to 14 hours prior to initiation of apheresis. A second dose may be given 10 to 14 hours prior to the third apheresis	BioLineRx	$24K for maximum number of doses
Augtyro™ (repotrectinib)	Kinase inhibitor	Rozlytrek®, Xalkori®	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	160 mg by mouth once a day for 14 days and then increase to 160 mg twice a day	Bristol-Myers Squibb	$29K for each month
Bimzelx® (bimekizumab-bkzx)	Interleukin-17A and F antagonist	Cosentyx®, Humira®, Skyrizi®, Stelara®, Taltz®	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	Administer 320 mg (two 160 mg injections) by subcutaneous injection at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter	UCB	$115K for first year of treatment
Exxua (gepirone extended-release)	Pyridinyl piperazine 5-HT1A receptor agonist	bupropion ER, duloxetine, escitalopram, mirtazapine	Treatment of major depressive disorder (MDD) in adults	Recommended starting dose is 18.2 mg by mouth once a day	Fabre-Kramer	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Loqtorzi™ (toripalimab-tpzi)	Programmed death receptor-1 (PD-1) blocking monoclonal antibody	Keytruda®, Opdivo®	In combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced naso-pharyngeal carcinoma (NPC) or as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum containing chemotherapy	Recommended dose in combination with cisplatin and gemcitabine is 240 mg administered intravenously every three weeks. As a single agent, recommended dose is 3 mg/kg intravenously every two weeks	Coherus Biosciences	Not available
Fruzaqla™ (fruquintinib)	Kinase inhibitor of VEGF receptors-1, -2, and -3	Lonsurf®, Stivarga®	Treatment of adults with metastatic colorectal cancer (mCRC) who have been previously treated with fluoro-pyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if rat sarcoma virus (RAS) wild-type and medically appropriate, an anti-epidermal growth factor receptor (EGFR) therapy	Recommended dosage is 5 mg by mouth once a day with or without food for the first 21 days of each 28-day cycle	Takeda	$25K for each 21-day course
Ojjaara (momelotinib)	Kinase inhibitor	Inrebic®, Jakafi®, Vonjo™	Treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia	200 mg by mouth once a day	GSK	$26,900 for each month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Omvoh™ (mirikizumab-mrkz)	Interleukin (IL)-23 inhibitor	Stelara®	Treatment of moderately to severely active ulcerative colitis (UC) in adults	Induction dose is 300 mg administered by intravenous infusion at Week 0, Week 4, and Week 8. Maintenance dose is 200 mg administered by subcutaneous injection at Week 12 and every 4 weeks thereafter.	Eli Lilly	$120K for first year
Opfolda™ (miglustat)	Enzyme stabilizer	Lumizyme®, Nexviazyme®	Opfolda in combination with Pombiliti for the treatment of adults with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT)	260 mg for adults weighing ≥50 kg and 195 mg for those weighing ≥40 kg to <50 kg every other week by mouth	Amicus Therapeutics	Combined cost with Pombiliti of $650K for each year
Pombiliti™ (cipaglucosidase alfa-atga	Hydrolytic lysosomal glycogen-specific enzyme	Lumizyme, Nexviazyme	Pombiliti in combination with Opfolda for the treatment of adults with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT)	20 mg/kg of body weight administered every other week by intravenous infusion over approximately 4 hours	Amicus Therapeutics	Combined cost with Opfolda of $650K for each year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Qlosi™ (pilocarpine)	Cholinergic agonist	Vuity®	Treatment of presbyopia in adults	Instill one drop in each eye. This can be repeated a second time after 2 to 3 hours for an effect up to 8 hours. Qlosi can be administered on a daily basis, or as needed, up to twice each day	Orasis	Not available
Rivfloza™ (nedosiran)	Lactate dehydrogenase A (LDHA-) directed small interfering ribonucleic acid (siRNA)	Oxlumo®	To lower urinary oxalate levels in children age 9 years and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2	Subcutaneous administration once a month with dosing provided in label based on actual body weight	Novo Nordisk	Not available
Ryzneuta® (efbemalenograstim alfa-vuxw)	Leukocyte growth factor	Neulasta®, Neupogen®	Decrease the incidence of infection, as manifested by febrile neutropenia, in adults with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	20 mg subcutaneous administration once per chemotherapy cycle	Evive Biotechnology	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Truqap™ (capivasertib)	Kinase inhibitor	Piqray®	In combination with fulvestrant for treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with ≥1 PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on ≥1 endocrine-based regimen(s) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy	400 mg by mouth twice a day (approximately 12 hours apart) with or without food for 4 days followed by 3 days off	AstraZeneca	$23K for each 28-day course
Velsipity™ (etrasimod)	Sphingosine 1-phosphate receptor modulator	Zeposia®	Treatment of moderately to severely active ulcerative colitis in adults	2 mg by mouth once a day	Pfizer	$75K for each year
Xphozah® (tenapanor)	Sodium hydrogen exchanger 3 (NHE3) inhibitor	lanthanum, sevelamer	Reduction of serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in people who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy	30 mg by mouth twice a day	Ardelyx	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Zepbound™ (tirzepatide)	Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist	Saxenda™, Wegovy®	Chronic weight management as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus (T2D), obstructive sleep apnea or cardiovascular disease)	Starting dosage is 2.5 mg by subcutaneous administration once a week for 4 weeks and then increase to 5 mg weekly. Recommended maintenance dosages are 5 mg, 10 mg, or 15 mg once a week.	Eli Lilly	$14K for each year
Zilbrysq® (zilucoplan)	Complement inhibitor	Rystiggo®, Soliris®, Ultomiris®, Vyvgart®, Vyvgart® Hytrulo	Treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive	Subcutaneous injection once a day based on body weight (16.6 mg/day to 32.4 mg/day)	UCB	Not available

New formulations

Brand (generic)	Description
Cabtreo™ (clindamycin phosphate/ adapalene/ benzoyl peroxide)	Clindamycin phosphate/adapalene/benzoyl peroxide combination product for the topical treatment of acne vulgaris in people age 12 years and older.
Combogesic® IV (acetaminophen/ ibuprofen)*	Acetaminophen plus ibuprofen intravenous infusion approved for the relief of mild to moderate pain and for the management of moderate to severe pain as an adjunct to opioid analgesics in adults, where an intravenous route of administration is considered clinically necessary.
Cosentyx® (secukinumab)*	Secukinumab intravenous (IV) formulation approved for use in adults with psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis (nr-axSpA).
Defencath™ (taurolidine/heparin)	Taurolidine and heparin catheter lock solution approved to reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter (CVC).
Empaveli® (pegcetacoplan)*	Pegcetacoplan single-use, on-body injector for self-administration approved for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
Entyvio® (vedolizumab)*	Vedolizumab subcutaneous pre-filled pen injector approved to treat moderately to severely active ulcerative colitis (UC) in adults.
Likmez™ (metronidazole)	Metronidazole oral suspension approved for trichomoniasis in adults, amebiasis in adults andchildren, and anaerobic bacterial infections in adults.
Penbraya™ (meningococcal groups A, B, C, W, and Y)*	Meningococcal vaccine approved for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in people age 10 years through 25 years.
Ryzumvi™ (phentolamine)	Phentolamine ophthalmic solution approved for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents.
Voquezna® (vonoprazan)	Vonoprazan tablets approved for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults and to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.

*Injectable

New formulations, continued

Brand (generic)	Description
Xalkori® (crizotinib)	Crizotinib 20 mg, 50 mg, and 150 mg oral pellets approved for all previously approved Xalkori indications.
Zituvimet (sitagliptin/ metformin)	Sitagliptin/metformin fixed-dose combination tablets approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Zituvio (sitagliptin)	Sitagliptin tablets approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Zymfentra® (infliximab-dyyb)*	Infliximab subcutaneous formulation approved for the maintenance treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease.

New indications

Brand (generic)	Description
Bosulif® (bosutinib)	Bosulif approved for children age 1 year and older with chronic phase (CP) Ph+ chronic myelogenous leukemia (CML) that is newly diagnosed (ND) or resistant or intolerant (R/I) to prior therapy. A new capsule dosage form was also approved in strengths of 50 mg and 100 mg.
Braftovi® (encorafenib) and Mektovi® (binimetinib)	Braftovi with Mektovi approved for adults with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation as detected by an FDA-approved test.
Cosentyx® (secukinumab)*	Cosentyx approved for the treatment of moderate to severe hidradenitis suppurativa (HS) in adults.
Enbrel® (etanercept)*	Enbrel approved for the treatment of active juvenile psoriatic arthritis (JPsA) in children age 2 years and older.
Exparel® (bupivacaine liposome)*	Exparel approved to include administration in adults as an adductor canal block and a sciatic nerve block in the popliteal fossa.
Hulio® (adalimumab-fkjp)*	Hulio approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Hyrimoz® (adalimumab-adaz)*	Hyrimoz approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.

*Injectable

New indications, continued

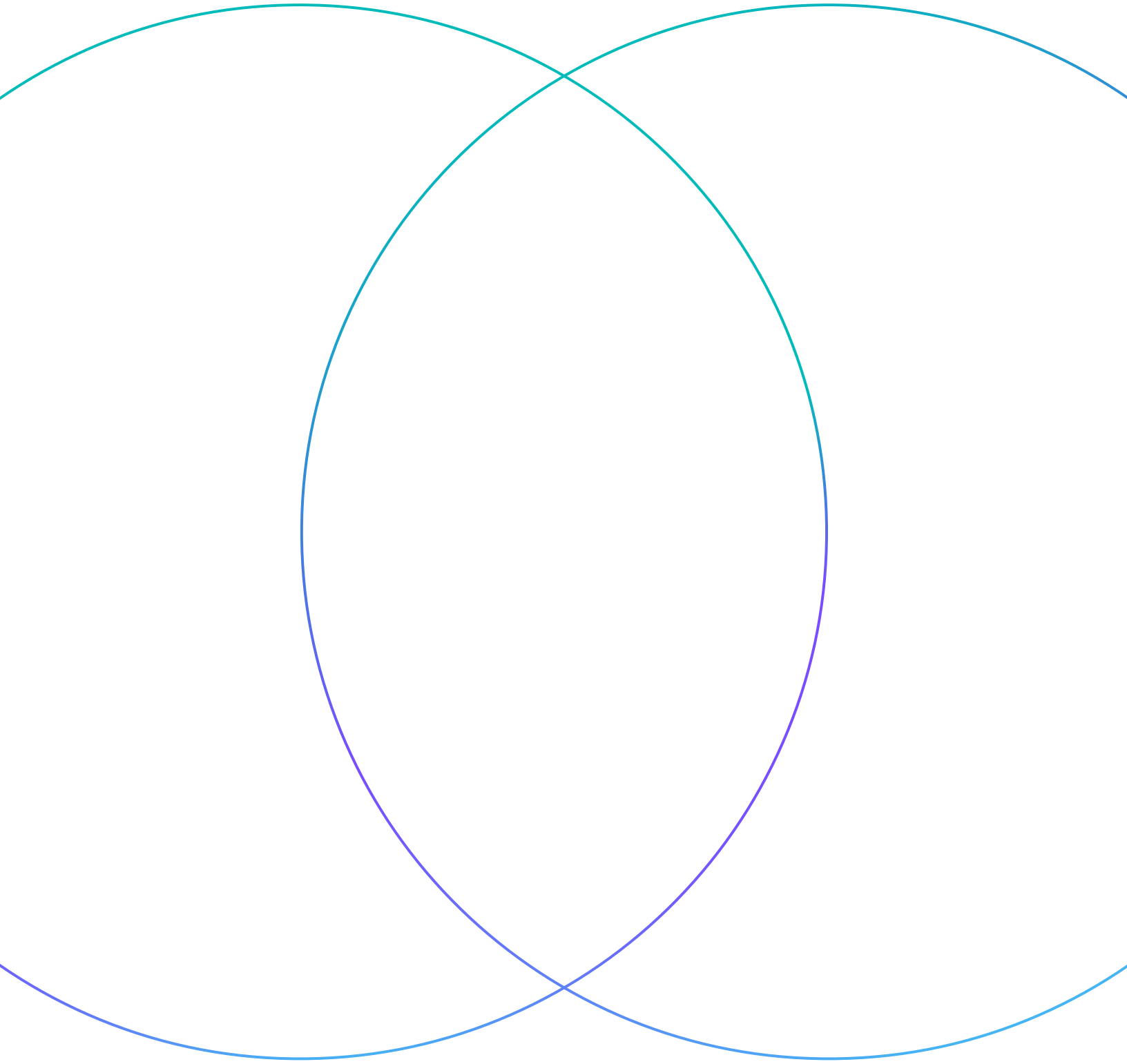
Brand (generic)	Description
Ilaris® (canakinumab)*	Ilaris approved for gout flares in adults when non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and when repeated courses of corticosteroids are not appropriate.
Jardiance® (empagliflozin)	Jardiance approved to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death, and hospitalization in adults with CKD at risk of progression.
Keytruda® (pembrolizumab)*	Keytruda approved with platinum-containing chemotherapy as neoadjuvant treatment, and with continuation of single-agent Keytruda as post-surgical adjuvant treatment for resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC).
Keytruda® (pembrolizumab)*	Keytruda approved in combination with gemcitabine and cisplatin for the treatment of locally advanced unresectable or metastatic biliary tract cancer (BTC).
Keytruda® (pembrolizumab)*	Keytruda approved with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.
Mekinist® (trametinib dimethyl sulfoxide)	Mekinist approved for extended age range of the tumor agnostic indication from children age 6 years and older to children age 1 year and older.
Opdivo® (nivolumab)*	Opdivo approved for the adjuvant treatment of adult and children age 12 years and older with completely resected stage IIB or IIC melanoma.
Orencia® (abatacept)*	Orencia approved for the treatment of children age 2 years to 17 years with active psoriatic arthritis (PsA).
Reblozyl® (luspatercept-aamt)*	Reblozyl approved for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions.
Rozlytrek® (entrectinib)	Rozlytrek approved to include children older than 1 month with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity and have progressed following treatment or have no satisfactory standard therapy.
Tafinlar® (dabrafenib mesylate)	Tafinlar approved for extended age range of the tumor agnostic indication from children age 6 years and older to children age 1 year and older.
Temodar® (temozolomide)*	Temodar approved for the adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma and the treatment of adults with refractory anaplastic astrocytoma.

*Injectable

New indications, continued

Brand (generic)	Description
Tibsovo® (Ivosidenib)	Tibsovo approved for adults with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
Veltassa® (patiromer)	Veltassa approved to include treatment of hyperkalemia in children age 12 years and older.
Vabysmo® (faricimab-svoa)*	Vabysmo approved for the treatment of macular edema following retinal vein occlusion (RVO).
Voxzogo® (vosoritide)*	Voxzogo approved to increase linear growth in children of all ages with achondroplasia with open epiphyses (growth plates).
Xtandi® (enzalutamide)	Xtandi approved for the treatment of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).
Yusimry™ (adalimumab-aqvh)*	Yusimry approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Zoryve (roflumilast)	Zoryve approved for the topical treatment of plaque psoriasis, including intertriginous areas, in children age 6 years to 11 years.

*Injectable



1063696MUEENCRX 12 23

carelon Rx