DrugInsights

Q2 2021

IngenioRx's *DrugInsights* provides a quarterly summary of new molecular entities, formulations, and indications approved by the Food and Drug Administration (FDA). 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 WAC*
Abecma (idecabtagene vicleucel)	Chimeric antigen receptor (CAR) T-cell therapy	First CAR T-cell therapy for multiple myeloma	Treatment of adults with relapsed or refractory multiple myeloma after 4 or more prior lines of therapy	A single dose of 300 to 460 x10^6 CAR-positive T cells administered intravenously	Bristol-Myers Squibb	$419,500 for the single dose of therapy
Amondys 45 (casimersen)	Antisense oligonucleotide	First therapy approved for this population	Duchenne muscular dystrophy (DMD) in people who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping	Intravenous infusion 30 mg/kg over 35 to 60 minutes, once weekly	Sarepta	$670K per single dose

*WAC = wholesale acquisition cost

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Empaveli (pegcetacoplan)	Complement inhibitor	Soliris, Ultomiris	Treatment of adults with paroxysmal nocturnal hemoglobinuria	1,080 mg by subcutaneous injection, twice weekly	Apellis Pharmaceuticals	$460K per year
Fotivda (tivozanib)	Vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI)	Cabometyx, Inlyta, Nexavar	Treatment of adults with relapsed or refractory advanced renal cell carcinoma (RCC) following 2 or more prior systemic therapies	1.34 mg once daily orally for 21 days on treatment followed by 7 days off treatment (28-day cycle)	AVEO Oncology	$24K per month
Jemperli (dostarlimab)	Programmed death receptor-1 (PD-1)–blocking antibody	Keytruda	Treatment of adults with mismatch repair deficient recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen	**Dose 1 through 4:** 500 mg via intravenous infusion every 3 weeks. **Subsequent dosing, beginning 3 weeks after dose 4 (dose 5 onward):** 1,000 mg every 6 weeks	GlaxoSmithKline	$15K per month
Nextstellis (drospirenone/ estetrol)	Progestin/ estrogen	Yasmin, Yaz	For use by females of reproductive potential to prevent pregnancy	1 tablet by mouth, at the same time every day	Mayne Pharma	$190 per month
Nulibry (fosdenopterin)	Cyclic pyranopterin monophosphate (cPMP)	First therapy approved for this indication	To reduce the risk of mortality in individuals with molybdenum cofactor deficiency (MoCD) Type A	Once daily intravenous infusion with titrated dosages determined by gestational age for individuals younger than 1 year. Individuals 1 year and older receive 0.9 mg/kg daily.	Origin Biosciences	$500K per year

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New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Pepaxto (melphalan flufenamide)	Peptide conjugated alkylating agent	First in class for this indication	Relapsed or refractory multiple myeloma	40 mg via intravenous infusion over 30 minutes, on day 1 of each 28-day cycle	Oncopeptides	$19K per month
Ponvory (ponesimod)	Sphingosine 1-phosphate (S1P) receptor modulator	Gilenya, Mayzent, Zeposia	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	Treatment is initiated with titrating doses orally from days 1 through 14. The maintenance dose starting at day 15 is 20 mg daily.	Janssen	$97K per year
Qelbree (viloxazine extended-release)	Selective norepinephrine reuptake inhibitor (SNRI)	Intuniv, Kapvay, Strattera	Attention deficit hyperactivity disorder (ADHD) in pediatric individuals, 6 to 17 years of age	100 mg or 200 mg orally, daily. Maximum dose of 400 mg, daily.	Supernus Pharmaceuticals	$600 per month
Rybrevant (amivantamab-vmjw)	Bispecific epidermal growth factor receptor (EGFR)-directed and mesenchymal epithelial transition (MET) receptor directed antibody	First product for non-small cell lung cancer (NSCLC) with exon 20 insertion mutations	Treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy	Dosage based on body weight. Administer via intravenous infusion weekly for 4 weeks, with initial dose as split infusion in Week 1 on Day 1 and Day 2, then administer every 2 weeks after.	Janssen	$9K or $12K per dose

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New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Zynlonta (loncastuximab tesirine)	CD19-directed antibody and alkylating agent conjugate	First antibody-drug conjugate specific for CD19	Treatment of adults with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma	0.15 mg/kg, every 3 weeks via intravenous infusion for 2 cycles 0.075 mg/kg, every 3 weeks for subsequent cycles	ADC Therapeutics	$188K per 8 cycles (6 months of treatment)

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New formulations

Brand (generic)	Description
Azstarys (serdexmethylphenidate/ dexmethylphenidate)	Serdexmethylphenidate (methylphenidate prodrug) and dexmethylphenidate combination approved for the treatment of ADHD in individuals ages 6 years and older.
Kimyrsa (oritavancin)[I]	Oritavancin one-hour infusion approved for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI).
Kloxxado (naloxone hydrochloride)	Naloxone 8 mg nasal spray approved for the emergency treatment of known or suspected opioid overdose, as indicated by respiratory and/or central nervous system depression.
Levothyroxine sodium[I]	Levothyroxine sodium 100 mcg/mL intravenous solution approved for the treatment of myxedema coma.
Myrbetriq (mirabegron)	Mirabegron extended-release oral suspension approved for neurogenic detrusor overactivity (NDO) in pediatric individuals ages 3 years and older and weighing 35 kg or more. The extended-release tablet formulation was also approved for this expansion.
Roszet (rosuvastatin calcium/ezetimibe)	Rosuvastatin calcium plus ezetimibe combination approved as an adjunct to diet in individuals with primary nonfamilial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C) and alone or as an adjunct to other LDL-C lowering therapies in individuals with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
Xolair (omalizumab)[I]	Omalizumab prefilled syringe formulation approved for self-injection across all approved U.S. indications.

[I] Injectable

New formulations (continued)

Brand (generic)	Description
Zegalogue (dasiglucagon)[I]	Glucagon analogue approved for the treatment of severe hypoglycemia in pediatric and adult individuals with diabetes ages 6 years and older.
Zynrelef (bupivacaine/ meloxicam)[I]	Bupivacaine and meloxicam extended-release solution approved in adults for soft-tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

[I] Injectable

New indications

Brand (generic)	Description
Actemra (tocilizumab)[I]	Actemra subcutaneous injection approved for slowing the rate of decline in pulmonary function in adults with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
Anavip (crotalidae immune FAB, equine)[I]	Anavip approved to include management of adult and pediatric individuals with copperhead and cottonmouth/water moccasin envenomations.
Arcalyst (rilonacept)[I]	Arcalyst approved for the treatment of recurrent pericarditis and to reduce the risk of recurrence in individuals 12 years and older.
Daptomycin[I]	Daptomycin injection approved to include pediatric individuals (1 to 17 years of age) for the treatment of complicated skin and skin structure infections (cSSSI) and for the treatment of *Staphylococcus aureus* bloodstream infections (bacteremia).
Diovan (valsartan)	Diovan approved to include individuals 1 to 5 years of age for the treatment of hypertension.
Evekeo ODT (amphetamine sulfate)	Evekeo ODT approved to include individuals 3 to 5 years of age for the treatment of ADHD.
Exparel (bupivacaine)[I]	Exparel approved to include use in individuals 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia.
Fabrazyme (agalsidase beta)[I]	Fabrazyme approved for the treatment of adult and pediatric individuals 2 years of age and older with Fabry disease.
Farxiga (dapagliflozin)	Farxiga approved to include reducing the risk of kidney function decline, kidney failure, cardiovascular (CV) death and hospitalization for heart failure (HF) in adults with chronic kidney disease (CKD) who are at risk of disease progression.
Ferriprox (deferiprone)	Ferriprox approved for the treatment of transfusional iron overload due to sickle cell disease (SCD) or other anemias in adult and pediatric individuals 3 years of age and older.

[I] Injectable

New indications (continued)

Brand (generic)	Description
Flucelvax Quadrivalent (inactivated influenza vaccine)[I]	Flucelvax Quadrivalent approved for active immunization in individuals 2 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.
Humira (adalimumab)[I]	Humira approved for the treatment of moderately to severely active ulcerative colitis in pediatric individuals 5 years of age and older.
Keytruda (pembrolizumab)[I]	Keytruda approved in combination with platinum and fluoropyrimidine-based chemotherapy for individuals with metastatic or locally advanced esophageal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above the gastroesophageal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiation.
Keytruda (pembrolizumab)[I]	Keytruda approved in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of individuals with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.
Lorbrena (lorlatinib)	Lorbrena approved for first-line treatment of individuals with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).
Natroba (spinosad)	Natroba approved for the treatment of scabies infestations in individuals 4 years of age and older.
Opdivo (nivolumab)[I]	Opdivo approved in combination with certain types of chemotherapy, for the initial treatment of individuals with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
Opdivo (nivolumab)[I]	Opdivo approved for individuals with completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.
Praluent (alirocumab)[I]	Praluent approved for adults with homozygous familial hypercholesterolemia (HoFH). Praluent is not intended to be used alone but instead added to other treatments for HoFH.
Ragwitek (short ragweed pollen allergen extract)[I]	Ragwitek approved to include individuals 5 to 17 years of age for the treatment of short ragweed pollen-induced allergic rhinitis.
Sarclisa (isatuximab)[I]	Sarclisa approved in combination with carfilzomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received 1 to 3 prior lines of therapy.
Trodelvy (sacituzumab govitecan-hziy)[I]	Trodelvy approved for use in adults with locally advanced or metastatic urothelial cancer (UC) who have previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

[I] Injectable

New indications (continued)

Brand (generic)	Description
Tyvaso (treprostinil)	Tyvaso approved for the treatment of individuals with pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.
Vyxeos (daunorubicin/ cytarabine)[I]	Vyxeos approved to treat newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric individuals ages 1 year and older.
Yescarta (axicabtagene ciloleucel)[I]	Yescarta approved for the treatment of adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

[I] Injectable