DrugInsights

Q3 2022

IngenioRx's *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 you 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)
Amvuttra™ (vutrisiran)	Small interfering ribonucleic acid	Onpattro®, Tegsedi®	Treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults	25 mg administered through an injection under the skin by a healthcare professional once every 3 months	Alnylam	$460K each year
Auvelity™ (dextromethorphan/ bupropion)	N-Methyl-D-Aspartate (NMDA) receptor antagonist and dopamine/ norepinephrine reuptake inhibitor	Bupropion	Treatment of adults with major depressive disorder	Initial dose is 1 tablet by mouth in the morning. After 3 days, the dose may be increased to 1 tablet twice a day (maximum dose) separated by at least 8 hours.	Axsome Therapeutics	Not available

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Vtama® (tapinarof)	Aryl hydrocarbon receptor agonist	Bryhali®, Sorilux, Zoryve™	Treatment of plaque psoriasis in adults	Apply thin layer of cream to affected areas once a day	Dermavant Sciences	$1,325 for each 60-gram tube
Zoryve™ (roflumilast)	Phosphodiesterase 4 (PDE4) inhibitor	Bryhali, Sorilux, Vtama	Treatment of plaque psoriasis, including intertriginous areas, in people age 12 years and older	Apply cream topically to affected areas once a day and rub in completely	Arcutis Biotherapeutics	$825 for each 60-gram tube
Zynteglo® (betibeglogene autotemcel)	Gene therapy	First gene therapy approved for this indication	Treatment of adults and children with beta-thalassemia who require regular red blood cell (RBC) transfusions	Each dose is created using the person's own bone marrow cells that are genetically modified and then readministered. This process involves multiple steps.	bluebird bio	$2.8 million per person for one-time treatment

New formulations

Brand (generic)	Description
Calquence® (acalabrutinib)	Acalabrutinib tablet formulation approved for adults with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) and for those with relapsed or refractory mantle cell lymphoma (MCL).
Drospirenone	Drospirenone chewable tablet approved for use by women of reproductive age to prevent pregnancy.
Hadlima™ (adalimumab-bwwd)*	Citrate-free, high concentration formulation of Hadlima approved for certain inflammatory conditions. Hadlima is a biosimilar to HUMIRA®.
Kyzatrex™ (testosterone undecanoate)	Testosterone undecanoate oral capsules approved for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

* Injectable

New formulations (continued)

Brand (generic)	Description
Priorix (measles, mumps, and Rubella vaccine)*	Measles, mumps, and rubella vaccine approved for active immunization for preventing measles, mumps, and rubella in people age 12 months and older.
Tadliq® (tadalafil)	Tadalafil oral suspension approved for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve ability to exercise.
Tyvaso DPI™ (treprostinil)	Treprostinil dry powder inhalation powder for treatment of people with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).
Ultomiris® (ravulizumab-cwvz)*	Ravulizumab subcutaneous on-body injection approved for treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS).
Venbysi™ XR (venlafaxine besylate extended-release)	Venlafaxine besylate extended-release tablets approved for treatment of major depressive disorder and generalized anxiety disorder in adults.
Zonisade™ (zonisamide)	Zonisamide oral suspension approved as adjunctive therapy for treatment of partial onset seizures in adults and children age 16 years and older.

* Injectable

New indications

Brand (generic)	Description
Abrilada™ (adalimumab-afzb)*	Abrilada approved for polyarticular juvenile idiopathic arthritis (JIA) to now include children age 2 years and older and for Crohn's disease (CD) to now include children age 6 years and older.
Amjevita™ (adalimumab-atto)*	Amjevita approved for polyarticular juvenile idiopathic arthritis (JIA) to now include children age 2 years and older and for Crohn's disease (CD) to now include children age 6 years and older.
Benlysta™ (belimumab)*	Benlysta approved to include children ages 5 to 17 years with active lupus nephritis who receive standard therapy.
Beovu® (brolucizumab-dbll)*	Beovu approved for treatment of diabetic macular edema (DME).
Breyanzi® (lisocabtagene maraleucel)*	Breyanzi approved for treatment of adults with large B-cell lymphoma (LBCL) after one prior therapy.

* Injectable

New indications (continued)

Brand (generic)	Description
CellCept® (mycophenolate mofetil)*	CellCept oral and injectable formulations approved for the prophylaxis of organ rejection in pediatric recipients of allogenic heart and allogenic liver transplants age 3 months and older combined with other immunosuppressants.
Diacomit® (stiripentol)	Diacomit approved for treatment of seizures associated with Dravet syndrome (DS) in people taking clobazam who are age 6 months and older and weigh 7 kg or more.
Dupixent® (dupilumab)*	Dupixent approved to include treatment of children ages 6 months to 5 years with moderate to severe atopic dermatitis not adequately controlled with topical prescription therapies or for when those therapies are not recommended.
Enhertu® (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for adults with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH) breast cancer who have received prior chemotherapy in the metastatic setting or developed a recurrence of the disease during or within 6 months of completing adjuvant chemotherapy.
Enhertu® (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for adults with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
Evrysdi® (risdiplam)	Evrysdi approved to include treatment of infants under 2 months old with spinal muscular atrophy (SMA).
Hadlima™ (adalimumab-bwwd)*	Hadlima approved for expanded use in polyarticular juvenile idiopathic arthritis (JIA) to include children age 2 years and older and for expanded use in Crohn's disease (CD) to include children age 6 years and older.
Hulio® (adalimumab-fkjp)*	Hulio approved for polyarticular juvenile idiopathic arthritis (JIA) to now include children age 2 years and older and for Crohn's disease (CD) to now include people age 6 years and older.
Hyrimoz™ (adalimumab-adaz)*	Hyrimoz approved for polyarticular juvenile idiopathic arthritis (JIA) to now include children age 2 years and older and for Crohn's disease (CD) to now include children age 6 years and older.
Imbruvica® (ibrutinib)	Imbruvica approved for children age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. An oral suspension formulation was also approved.
Imcivree® (setmelanotide)*	Imcivree approved for chronic weight management in adults and children age 6 years and older with obesity due to Bardet-Biedl Syndrome (BBS).
Kymriah® (tisagenlecleucel)*	Kymriah approved for treatment of adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
Krystexxa® (pegloticase)*	Krystexxa approved for accompanying use with methotrexate for treating people with uncontrolled gout to bring about a complete response to therapy.

* Injectable

New indications (continued)

Brand (generic)	Description
Kyprolis® (carfilzomib)*	Kyprolis approved in combination with SARCLISA® (isatuximab-irfc) and dexamethasone (Isa-Kd) for treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received one to three lines of therapy.
Mekinist® (trametinib) and Tafinlar® (dabrafenib)	Mekinist plus Tafinlar approved for treatment of adults and children age 6 years and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no other adequate treatment options.
Mirena® (levonorgestrel)	Mirena intrauterine device approved for use of up to 8 years for prevention of pregnancy.
Myfembree® (relugolix, estradiol, and norethindrone acetate)	Myfembree approved for treatment of endometriosis-associated pain.
Nubequa® (darolutamide)	Nubequa approved in combination with docetaxel for adults with metastatic hormone-sensitive prostate cancer (mHSPC).
Olumiant® (baricitinib)	Olumiant approved for treatment of adults with severe alopecia areata.
Opvido® (nivolumab)*	Opdivo approved in combination with fluoropyrimidine- and platinum-containing chemotherapy and OPDIVO plus YERVOY® (ipilimumab injection) as a first-line treatment for adults with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) regardless of programmed death-ligand 1(PD-L1) status.
Opzelura™ (ruxolitinib)	Opzelura approved for topical treatment of nonsegmental vitiligo in adult and children age 12 years and older.
Qsymia® (phentermine/ topiramate extended-release)	Qsymia approved for chronic weight management in children age 12 years and older who are obese. Obese is defined as a body mass index (BMI) of 95th percentile or greater when standardized for age and sex.
Rebinyn® (coagulation factor IX, recombinant)*	Rebinyn approved to include use in adults and children with hemophilia B for routine prophylaxis to reduce the frequency of bleeding events.
Riabni™ (rituximab-arrx)*	Riabni, a biosimilar for Rituxan®, approved in combination with methotrexate for adults with moderate to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.
Skyrizi® (risankizumab-rzaa)*	Skyrizi approved for treatment of adults with moderately to severely active Crohn's disease (CD).

* Injectable

New indications (continued)

Brand (generic)	Description
Stelara® (ustekinumab)*	Stelara approved to include treatment of children age 6 years and older with active psoriatic arthritis.
Tibsovo® (ivosidenib)	Tibsovo approved in combination with azacitidine for newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase 1(IDH1) mutation, as detected by an FDA-approved test in adults age 75 years or older, or who have comorbidities that prevent use of intensive induction chemotherapy.
Vaxneuvance™ (pneumococcal 15-valent conjugate vaccine)*	Vaxneuvance approval expanded for active immunization for prevention of invasive disease caused by certain *Streptococcus pneumoniae* serotypes in people age 6 weeks and older.
Xalkori® (crizotinib)	Xalkori approved for adult and children age 1 year and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase (ALK)-positive myofibroblastic tumors (IMT).
Xofluza® (baloxavir marboxil)	Xofluza approved for treatment of acute uncomplicated influenza in otherwise healthy children age 5 years to younger than 12 years who have been symptomatic for no more than 48 hours. Additionally, the FDA approved Xofluza for prevention (post-exposure prophylaxis) of influenza in children age 5 years to younger than 12 years following contact with someone with influenza.
Zulresso® (brexanolone)*	Zulresso approved to expand to include people age 15 years and older diagnosed with postpartum depression.

* Injectable