# DrugInsights

Q1 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 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* |
|---|---|---|---|---|---|---|
| Adbry (tralokinumab-ldrm) | Interleukin-13 antagonist | Dupixent | Moderate-to-severe atopic dermatitis (AD) in adults whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable | Initial dose of 600 mg, followed by 300 mg, given every other week. A dose of 300 mg every 4 weeks may be considered for those below 100 kg with clear or almost-clear skin after 16 weeks. | LEO Pharma | $3,400 each month |

* WAC = wholesale acquisition cost

**New molecular entities (continued)**

| Brand (generic) | Therapeutic class | Competitors | Indication(s) | Dosage | Manufacturer | Estimated WAC* |
|---|---|---|---|---|---|---|
| Apretude (cabotegravir extended release) | HIV-1 integrase strand transfer inhibitor (INSTI) | Descovy, emtricitabine/ tenofovir disoproxil fumarate | In at-risk adults and adolescents weighing at least 35 kg for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) | Single injection given 1 month apart for 2 consecutive months and continue with the injections every 2 months thereafter | ViiV Healthcare | $3,700 for each vial |
| Cibinqo (abrocitinib) | Janus kinase (JAK) inhibitor | Adbry, Dupixent, Rinvoq | Treatment of adults with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable | 100 mg orally, once daily. If adequate response is not achieved after 12 weeks, consider increasing to 200 mg, once daily. | Pfizer | $4,900 each month |
| Enjaymo (sutimlimab-jome) | Monoclonal antibody, complement inhibitor | First approved treatment for this indication | To decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease | Administered by intravenous infusion on days 0 and 7, and then every 2 weeks. The dose is based on body weight. | Bioverativ | $1,800 for each vial |
| Fyarro (sirolimus [protein bound]) | mTOR kinase inhibitor | First approved agent for this indication | Treatment of adults with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) | 100 mg/m$^2$ on days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity | Aadi Bioscience, Inc. | $470K each year |
| Kimmtrak (tebentafusp-tebn) | T cell receptor (TCR) bispecific immunotherapy | First approved treatment for this indication | Treatment of human leukocyte antigen (HLA)-A*02:01-positive adults with unresectable or metastatic uveal melanoma (mUM) | Recommended dosage is 20 mcg given by intravenous (IV) infusion on day 1, 30 mcg IV on day 8, 68 mcg IV on day 15, and 68 mcg IV once every week thereafter | Immunocore | $18,760 for each vial |

* WAC = wholesale acquisition cost

**New molecular entities (continued)**

| Brand (generic) | Therapeutic class | Competitors | Indication(s) | Dosage | Manufacturer | Estimated WAC* |
|---|---|---|---|---|---|---|
| Leqvio (inclisiran) | Small interfering RNA (siRNA) directed to proprotein convertase subtilisin kexin type 9 (PCSK9) mRNA | Praluent, Repatha | Adjunct to diet and maximally tolerated statins for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C) | 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months | Novartis | $9,750 for first year; $6,500 for subsequent years |
| Livtencity (maribavir) | Benzimidazole antiviral drug | Cidofovir, foscarnet, ganciclovir, valganciclovir | Treatment of adults and pediatric individuals (12 years of age and older and weighing 35 kg or more) with post-transplant cytomegalovirus (CMV) infection or disease that is refractory to treatment | 400 mg, twice daily | Takeda | $220 for each tablet |
| Pyrukynd (mitapivat) | Pyruvate kinase activator | First approved treatment for this indication | Treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency | Starting dose is 5 mg orally, twice daily, and then titrated every 4 weeks, up to the maximum dose of 50 mg, twice daily | Agios Pharmaceuticals | $335K each year |
| Quviviq (daridorexant) | Orexin receptor antagonist | Belsomra, Dayvigo | Treatment of adults with insomnia characterized by difficulties with sleep onset and/or sleep maintenance | 25 mg to 50 mg orally, no more than once each night within 30 minutes of going to bed (with at least 7 hours remaining before planned awakening) | Idorsia Pharmaceuticals | Not available |

* WAC = wholesale acquisition cost

**New molecular entities (continued)**

| Brand (generic) | Therapeutic class | Competitors | Indication(s) | Dosage | Manufacturer | Estimated WAC* |
|---|---|---|---|---|---|---|
| Recorlev (levoketoconazole) | Cortisol synthesis inhibitor | Ketoconazole off-label use | Treatment of adults with Cushing's syndrome with endogenous high cortisol levels where surgery is not an option or has not been curative | Starting at 150 mg orally, twice daily, titrating by 150 mg increments (no more frequently than every 2 to 3 weeks) until adequate clinical response, up to a maximum 600 mg, twice daily (1,200 mg each day) | Xeris Pharmaceuticals | $790K each year |
| Tarpeyo (budesonide delayed release) | Corticosteroid | First approved agent for this indication | Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g | 16 mg orally, once a day | Calliditas Therapeutics AB | $14K each month |
| Tezspire (tezepelumab-ekko) | Thymic stromal lymphopoietin (TSLP) blocker | Dupixent | Add-on maintenance treatment of adult and pediatric individuals age 12 years and older with severe asthma | 210 mg administered subcutaneously, once every 4 weeks | Amgen | $43K each year |

* WAC = wholesale acquisition cost

**New molecular entities (continued)**

| Brand (generic) | Therapeutic class | Competitors | Indication(s) | Dosage | Manufacturer | Estimated WAC* |
|---|---|---|---|---|---|---|
| Vabysmo (faricimab-svoa) | Vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor | Eylea, Lucentis | Treatment of adults with neovascular (wet) age-related macular degeneration (nAMD) or diabetic macular edema (DME) | **Wet AMD:** 6 mg, administered by intravitreal injection every 4 weeks for 4 months, followed by every 8-, 12-, or 16-weeks dosing, based on disease activity<br><br>**DME:** 6 mg every 4 weeks for 4 months, followed by either every 4- or every 8-week dosing, based on disease activity for a year or 6 mg every 4 weeks for 6 months, followed by every 8-week dosing for a year | Genentech | $2,190 for each dose |
| Vyvgart (efgartigimod alfa-fcab) | Neonatal Fc receptor blocker | Soliris | Treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive | 10 mg/kg through intravenous infusion over one hour, once weekly, for 4 weeks. In individuals weighing 120 kg or more, recommended dose is 1,200 mg for each infusion. | argenx | $225K each year for average individual |

* WAC = wholesale acquisition cost

## New formulations

| Brand (generic) | Description |
|---|---|
| Dartisla ODT (glycopyrrolate) | Glycopyrrolate orally disintegrating tablets approved in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. |
| Entadfi (finasteride/ tadalafil) | Finasteride and tadalafil combination approved for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks. |
| Fleqsuvy (baclofen) | Baclofen oral suspension approved for the treatment of spasticity resulting from multiple sclerosis (MS), particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. |
| Lyvispah (baclofen) | Baclofen oral granules approved for the treatment of spasticity resulting from MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah may also be of value in people with spinal cord injuries and other spinal cord diseases. |
| Nucala (mepolizumab)[I] | Mepolizumab 40 mg prefilled syringe approved as add-on maintenance treatment for children 6 to 11 years of age with severe asthma and with an eosinophilic phenotype. |
| PreHevbrio (recombinant hepatitis B vaccine)[I] | Recombinant hepatitis B vaccine approved for the prevention of infection caused by all known subtypes of hepatitis B virus (HBV) in adults age 18 years and older. |
| Ryaltris (olopatadine hydrochloride/mometasone furoate) | Olopatadine hydrochloride and mometasone furoate combination nasal spray approved for the treatment of symptoms of seasonal allergic rhinitis in adults and pediatric individuals 12 years of age and older. |
| Tascenso ODT (fingolimod lauryl sulfate) | Fingolimod orally disintegrating tablets approved for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in pediatric individuals 10 years of age and older and weighing less than or equal to 40 kg. |
| Xaciato (clindamycin phosphate) | Clindamycin phosphate vaginal gel approved for the treatment of bacterial vaginosis in females 12 years of age and older. |

[I] Injectable.

## New indications

| Brand (generic) | Description |
|---|---|
| Caplyta (lumateperone) | Caplyta approved for the treatment of depressive episodes associated with bipolar I or II disorder in adults, as monotherapy and as adjunctive therapy with lithium or valproate. |

* Injectable.

**New indications (continued)**

| Brand (generic) | Description |
|---|---|
| Cosentyx (secukinumab)* | Cosentyx approved for the treatment of active enthesitis-related arthritis (ERA) in individuals 4 years and older and active psoriatic arthritis (PsA) in individuals 2 years and older. |
| Delstrigo (doravirine/lamivudine/ tenofovir disoproxil fumarate) | Delstrigo approved for the treatment of HIV-1 in pediatric individuals weighing at least 35 kg. |
| Darzalex Faspro (daratumumab/ hyaluronidase-fihj)* | Darzalex Faspro approved in combination with carfilzomib plus dexamethasone for adults with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy. |
| Descovy (emtricitabine/tenofovir alafenamide fumarate) | Descovy approval expanded to include treatment of HIV-1 infection in pediatric individuals at least 2 years of age and weighing at least 14 kg. |
| Injectafer (ferric carboxymaltose)* | Injectafer approved for pediatric individuals 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron. |
| Keytruda (pembrolizumab)* | Keytruda approved for the adjuvant treatment of adult and pediatric (12 years and older) individuals with stage IIB or IIC melanoma following complete resection. Additionally, the FDA expanded the indication for Keytruda as adjuvant treatment for stage III melanoma following complete resection to include pediatric individuals (12 years and older). |
| Orencia (abatacept)* | Orencia approved for the prophylaxis of acute graft-versus-host disease (aGVHD) in combination with certain immunosuppressants. |
| Otezla (apremilast) | Otezla approved for the treatment of adults with plaque psoriasis who are candidates for phototherapy or systemic therapy regardless of severity level. |
| Oxbryta (voxelotor) | Oxbryta approved to treat sickle cell disease in pediatric individuals age 4 to 11 years. A dispersible, once-daily tablet dosage form was also approved. |
| Pifeltro (doravirine) | Pifeltro approved for the treatment of HIV-1 in pediatric individuals weighing at least 35 kg. |
| Rexulti (brexpiprazole) | Rexulti approved for the treatment of schizophrenia in individuals age 13 to 17 years. |
| Rinvoq (upadacitinib) | Treatment of adults and children 12 years of age and older with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. |

* Injectable.

**New indications (continued)**

| Brand (generic) | Description |
|---|---|
| Rinvoq (upadacitinib) | Rinvoq approved for the treatment of adults with active psoriatic arthritis who have had an inadequate response, or intolerance to, tumor necrosis factor (TNF) inhibitors. |
| Rituxan (rituximab)* | Rituxan approved in combination with chemotherapy for pediatric individuals (younger than 6 months to younger than 18 years) with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt's lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL). |
| Siklos (hydroxyurea) | Siklos approved to include adults to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric individuals (2 years of age and older) with sickle cell anemia with recurrent moderate-to-severe painful crises. |
| Solosec (secnidazole) | Solosec approved for the treatment of bacterial vaginosis and trichomoniasis caused by *Trichomonas vaginalis* in individuals 12 years of age and older. |
| Skyrizi (risankizumab-rzaa)* | Skyrizi approved for the treatment of adults with active PsA. |
| Veklury (remdesivir)* | Veklury approved for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. |
| Vocabria (cabotegravir) | Vocabria approved as oral lead-in to assess the tolerability of cabotegravir before administration of cabotegravir extended-release injectable suspension for HIV-1 PrEP and oral therapy for individuals who will miss planned injection dosing with cabotegravir injectable for HIV-1 PrEP. |
| Vonvendi (recombinant von Willebrand factor)* | Vonvendi approved for routine prophylaxis to reduce the frequency of bleeding episodes in individuals with severe type 3 von Willebrand disease (VWD) receiving on-demand therapy. |
| Xigduo XR (dapagliflozin, metformin hydrochloride) | Xigduo XR approved to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (New York Heart Association class II–IV) with reduced ejection fraction. |
| Xarelto (rivaroxaban) | Xarelto approved to treat venous thromboembolism (VTE) and to reduce the risk of VTE recurring in pediatric individuals from birth to younger than 18 years who have received at least five days of injectable or intravenous treatment for blood clots. It was also approved to prevent blood clots in pediatric individuals 2 years and older with congenital heart disease after the Fontan procedure, a type of open-heart surgery. An oral suspension dosage form was also approved. |

* Injectable.

**New indications (continued)**

| Brand (generic) | Description |
|---|---|
| Xeljanz, XR (tofacitinib) | Xeljanz and Xeljanz XR approved for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers. |
| Zepatier (elbasvir/grazoprevir) | Zepatier approved for the treatment of individuals age 12 to younger than 18 years with chronic hepatitis C (HCV) genotype 1 or 4 infection without cirrhosis. |
| Zynrelef (bupivacaine/ meloxicam)* | Zynrelef approved in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower-extremity, total-joint arthroplasty surgical procedures. |

* Injectable.