pharmpiX
POWERED BY ONEARK

PHARMNOTES

October 2023

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2025

Table of Contents

Drug Safety Alert Notification

- No drug safety communication published in October.

New FDA-Approved Drug Products

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
VELSIPITY™ (ETRASIMOD) TABLETS	PFIZER INC	10/12/2023

THERAPEUTIC CLASS
Inflammatory Bowel Agents

FDA-APPROVED INDICATION(S)
Velsipity™ is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults.

DOSAGE AND ADMINISTRATION
- Recommended dosage: 2mg orally once daily.
- Swallow the whole tablet, with or without food.
- Perform the following evaluations prior to Velsipity™ initiation: Complete Blood Count (CBC), Cardiac Evaluation, Liver Function Tests, Ophthalmic Assessment, Vaccinations.

DOSAGE FORMS AND STRENGTHS
Tablets: 2mg of etrasimod

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- In the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure.
- History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

WARNINGS AND PRECAUTIONS
- *Infections:* May increase the risk of infections. Obtain a complete blood count (CBC) before initiation of treatment. Monitor for infection during treatment and for 5 weeks after discontinuation. Consider interruption of treatment if a serious infection develops. Avoid use of live attenuated vaccines during and for up to 5 weeks after treatment.
- *Bradyarrhythmia and Atrioventricular Conduction Delays*: May result in a transient decrease in heart rate and AV conduction delays. Obtain an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting treatment. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate.
- *Liver Injury:* Elevations of aminotransferases may occur. Obtain transaminase and bilirubin levels before initiating Velsipity™. Discontinue if significant liver injury is confirmed.
- *Macular Edema*: May increase the risk of macular edema. Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment with Velsipity™. Periodically conduct an evaluation of the fundus, including the macula, while on therapy and any time there is a change in vision. Consider discontinuing Velsipity™ if macular edema develops.

WARNINGS AND PRECAUTIONS (cont.)
- *Increased Blood Pressure:* Monitor blood pressure during treatment.
- *Fetal Risk:* May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for one week after stopping Velsipity™.
- *Malignancies:* Obtain a skin examination prior to or shortly after the start of treatment and periodically during treatment, especially if risk factors. Promptly evaluate suspicious skin lesions.
- *Respiratory Effects:* May cause a decline in pulmonary function. Assess pulmonary function (e.g., spirometry) if clinically indicated.
- *Unintended Additive Immune System Effects from Prior Treatment with Immunosuppressive or Immune-Modulating Drugs:* Consider the half-life and mode of action of prior therapies.
- *Immune System Effects After Stopping Velsipity™:* If using concomitant immunosuppressants, monitor patients for infectious complications for up to 5 weeks after the last dose of Velsipity™.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥5%) are headache, elevated liver test, and dizziness.

Continues on the next slide

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
VELSIPITY™ (ETRASIMOD) TABLETS	PFIZER INC	10/12/2023

THERAPEUTIC CLASS
Inflammatory Bowel Agents

FDA-APPROVED INDICATION(S)
Velsipity™ is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis in adults.

DOSAGE AND ADMINISTRATION
- Recommended dosage: 2mg orally once daily.
- Swallow the whole tablet, with or without food.
- Perform the following evaluations prior to Velsipity™ initiation: Complete Blood Count (CBC), Cardiac Evaluation, Liver Function Tests, Ophthalmic Assessment, Vaccinations

DOSAGE FORMS AND STRENGTHS
Tablets: 2mg of etrasimod

Orphan status: No

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS
- *Pregnancy:* May cause fetal harm when administered to a pregnant woman.
- *Females and Males of Reproductive Potential:* Females of reproductive potential should be counseled on the potential for a serious risk to the fetus and the need of contraception during treatment with Velsipity™.
- *Hepatic Impairment:* Use of Velsipity™ with hepatic impairment is not recommended.

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
ZILBRYSQ™ (ZILUCOPLAN SODIUM) INJECTION	UCB INC	10/17/2023

THERAPEUTIC CLASS:
Complement inhibitor

FDA-APPROVED INDICATION(S)
Zilbrysq™ is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

DOSAGE AND ADMINISTRATION
- Before initiating Zilbrysq™ obtain baseline lipase and amylase levels.
- Vaccinate patients for meningococcal infection according to ACIP recommendations at least 2 weeks prior to administering the first dose of Zilbrysq™.
- The recommended dosage of Zilbrysq™ is given once daily as a subcutaneous injection and is dependent on actual body weight.

Body Weight	Once Daily Dosage	Plunger Rod Color of Prefilled Syringe
less than 56 kg	16.6 mg	RUBINE RED
56 kg to less than 77 kg	23 mg	ORANGE
77 kg and above	32.4 mg	DARK BLUE

DOSAGE FORMS AND STRENGTHS
Injection: 16.6mg/0.416mL, 23mg/0.574mL, or 32.4mg/0.81mL zilucoplan in single-dose prefilled syringes.

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with unresolved *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: SERIOUS MENINGOCOCCAL INFECTIONS**
  - Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; Zilbrysq™ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.
  - Complete or update meningococcal vaccination at least 2 weeks prior to administering the first dose of Zilbrysq™, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
  - Persons receiving Zilbrysq™ are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.
  - Zilbrysq™ is available only through REMS program.

WARNINGS AND PRECAUTIONS (cont.)
- *Other Infections*: Use caution when administering Zilbrysq™ to patients with any other systemic infection.
- Pancreatitis and pancreatic cysts have been reported in patients treated with Zilbrysq™. Discontinue Zilbrysq™ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS
- Most common adverse reactions (≥10%) in patients with gMG were injection site reactions, upper respiratory tract infection, and diarrhea.

USE IN SPECIFIC POPULATIONS
- *Pregnancy:* May cause fetal harm when administered to a pregnant woman.
- *Lactation*: Developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zilbrysq™ and any potential adverse effects on the breastfed infant from Zilbrysq™ or from the underlying maternal condition.

Orphan status: Yes

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
BIMZELX™ (BIMEKIZUMAB-BKZX) INJECTION	UCB INC	10/17/2023

THERAPEUTIC CLASS:
Immunological Agents

FDA-APPROVED INDICATION(S)
Bimzelx™ is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

DOSAGE AND ADMINISTRATION
- Administer 320mg (two 160mg injections) by subcutaneous injection at weeks 0, 4, 8, 12 and 16, then every 8 weeks thereafter. For patients weighing ≥120kg, consider a dose of 320mg every 4 weeks after Week 16.
- Prior to treatment:
  - Evaluate patients for tuberculosis infection.
  - Test liver enzymes, alkaline phosphatase, and bilirubin.
  - Complete all age-appropriate vaccinations as recommended by current immunization guidelines.

DOSAGE FORMS AND STRENGTHS
Injection: 160mg/mL in a single-dose prefilled syringe or single-dose prefilled autoinjector.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- *Suicidal Ideation and Behavior (SI/B):* May increase risk of SI/B. Advise patients, their caregivers, and families to monitor for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise them to promptly seek medical attention or call the National Suicide and Crisis Lifeline at 988. Carefully weigh risks and benefits of treatment with Bimzelx™ in patients with a history of severe depression and/or suicidal ideation or behavior.
- *Infections:* May increase risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer Bimzelx™ until the infection resolves.
- *Tuberculosis (TB):* Avoid use in patients with active TB. Initiate treatment of latent TB prior to Bimzelx™ treatment.
- *Liver Biochemical Abnormalities:* Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management. Permanently discontinue use of Bimzelx™ in patients with causally - associated combined elevations of transaminases and bilirubin.
- *Inflammatory Bowel Disease (IBD):* Cases of IBD were reported in clinical trials with IL-17 inhibitors, including Bimzelx™. Avoid use of Bimzelx™ in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 1%) are upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
AGAMREE™ (VAMOROLONE) ORAL SUSPENSION	SANTHERA PHARMA	10/26/2023

THERAPEUTIC CLASS:
Immunosuppressants

FDA-APPROVED INDICATION(S)
Agamree™ is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
- The recommended dosage is 6mg/kg taken orally daily preferably with a meal, up to a maximum daily dosage of 300mg for patients weighing more than 50kg.
- In patients with mild to moderate hepatic impairment, the recommended dosage is 2mg/kg taken orally once daily preferably with a meal, up to a maximum daily dosage of 100mg for patients weighing more than 50kg.
- Decrease dosage gradually when administered for more than one week.

DOSAGE FORMS AND STRENGTHS
Oral suspension: 40mg/mL

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- Hypersensitivity to vamorolone or any of the inactive ingredients in Agamree™.

WARNINGS AND PRECAUTIONS
- *Alterations in Endocrine Function:* Hypothalamic-pituitary-adrenal axis suppression, cushingoid features, and hyperglycemia can occur. Monitor patients for these conditions with chronic use of Agamree™.
- *Immunosuppression and Increased Risk of Infection:* Increased risk of new infections, exacerbation, dissemination, or reactivation of latent infections, which can be severe and at times fatal; signs and symptoms of infections may be masked.
- *Alterations in Cardiovascular/Renal Function:* Monitor for elevated blood pressure and monitor sodium and potassium levels in patients chronically treated with Agamree™.
- *Gastrointestinal Perforation:* Increased risk in patients with certain GI disorders; signs and symptoms may be masked.
- *Behavioral and Mood Disturbances:* May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis.
- *Effects on Bones:* Monitor for decreases in bone mineral density with chronic use of Agamree™.
- *Ophthalmic Effects:* May include cataracts, infections, and glaucoma; monitor intraocular pressure in patients chronically treated with Agamree™.

WARNINGS AND PRECAUTIONS (cont.)
- *Vaccination:* Do not administer live or live attenuated vaccines to patients receiving immunosuppressive doses of corticosteroids. Administer live attenuated or live vaccines at least 4 to 6 weeks prior to starting Agamree™.

ADVERSE REACTIONS
- Most common adverse reactions (>10% for Agamree™ and greater than placebo) are cushingoid features, psychiatric disorders, vomiting, weight increased, and vitamin D deficiency.

DRUG INTERACTIONS
- *Strong CYP3A4 Inhibitors*: Maximum recommended daily dose is 4 mg/kg up to a maximum daily dosage of 200 mg for patients weighing more than 50 kg.

USE IN SPECIFIC POPULATIONS
- *Hepatic Impairment:* Moderate hepatic impairment increases vamorolone exposure. Reduce the dosage in patients with mild to moderate hepatic impairment.

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
OMVOH™ (MIRIKIZUMAB-MEKZ) INJECTION	ELI LILLY AND CO	10/26/2023

THERAPEUTIC CLASS:
Immunological Agents

FDA-APPROVED INDICATION(S)
Omvoh™ is an interleukin-23 antagonist indicated for the treatment of moderately to severely ulcerative colitis in adults.

DOSAGE AND ADMINISTRATION
- Prior to treatment initiation patients should be evaluated for tuberculosis (TB) infection; liver enzymes and bilirubin levels. And must be completed all age-appropriate vaccinations to current immunization guidelines.
- Recommended induction dosage: 300mg administered by intravenous infusion over at least 30 minutes at weeks 0, 4 and 8.
- Recommended maintenance dosage: 200mg administered by subcutaneous injection (given as two consecutive injections of 100mg each) at week 12 and every 4 weeks thereafter.

DOSAGE FORMS AND STRENGTHS
- *Intravenous infusion:* Injection: 300mg/ 15mL (20mg/mL) solution in a single-dose vial.
- *Subcutaneous injection:* Injection: 100mg/mL solution in a single-dose prefilled pen.

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- History of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

WARNINGS AND PRECAUTIONS
- *Hypersensitivity Reactions:* Serious hypersensitivity reactions, including anaphylaxis and infusion-related reactions, have been reported. If a severe hypersensitivity reaction occurs, discontinue and initiate appropriate treatment.
- *Infections:* Omvoh™ may increase the risk of infection. Do not initiate treatment with Omvoh™ in patients with a clinically important active infection until the infection resolves or is adequately treated. If a serious infection develops, do not administer Omvoh™ until the infection resolves.
- *Tuberculosis:* Do not administer Omvoh™ to patients with active TB infection. Monitor patients receiving Omvoh™ for signs and symptoms of active TB during and after treatment.
- *Hepatotoxicity:* Drug-induced liver injury has been reported. Monitor liver enzymes and bilirubin levels at baseline and for at least 24 weeks of treatment and thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded.
- *Immunizations*: Avoid use of live vaccines.

ADVERSE REACTIONS
- Most common adverse reactions (≥2%) are:
  - *Induction:* upper respiratory tract infections and arthralgia.
  - *Maintenance:* upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection.

New Molecular Entity

DRUG NAME	MANUFACTURER	APPROVAL DATE
LOQTORZI™ (TORIPALIMAB-TPZI) INJECTION	COHERUS BIOSCIENCES INC	10/27/2023

THERAPEUTIC CLASS:
Antineoplastics

FDA-APPROVED INDICATION(S)
Loqtorzi™ is a programmed death receptor-1 (PD-1)- blocking antibody indicated:

- In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC).
- 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.

DOSAGE AND ADMINISTRATION

- In combination with cisplatin and gemcitabine: 240 mg intravenously every three weeks
- As a single agent: 3 mg/kg intravenously every two weeks
- First Infusion: Infuse over 60 minutes.
- Subsequent Infusions: If no infusion-related reactions occurred during the first infusion, subsequent infusions may be administered over 30 minutes.

DOSAGE FORMS AND STRENGTHS
Injection: 240 mg/6 mL (40 mg/mL) solution in a single-dose vial.

SAFETY PROFILE

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

- *Immune-Mediated Adverse Reactions:* Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune mediated hepatitis, immune-mediated endocrinopathies, immune mediated nephritis with renal dysfunction, immune mediated dermatologic adverse reactions, and solid organ transplant rejection.
- *Infusion-related reactions:* Interrupt, slow the rate of infusion, or permanently discontinue Loqtorzi™ based on the severity of reaction.
- *Complications of allogeneic HSCT:* Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.
- *Embryo-fetal toxicity:* Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective method of contraception.

ADVERSE REACTIONS

- *Loqtorzi™ in combination with Cisplatin and Gemcitabine:* The most common adverse reactions (≥ 20%) are nausea, vomiting, decreased appetite, constipation, hypothyroidism, rash, pyrexia, diarrhea, peripheral neuropathy, cough, musculoskeletal pain, upper respiratory infection, insomnia, dizziness, and malaise.
- *Loqtorzi™ as a Single Agent:* The most common adverse reactions (≥20%) are fatigue, hypothyroidism, and musculoskeletal pain.

USE IN SPECIFIC POPULATIONS

- *Pregnancy:* Based on its mechanism of action, Loqtorzi™ can cause fetal harm when administered to a pregnant woman.
- *Lactation:* Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed.
- *Females and Males of Reproductive Potential:* Verify the pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to use effective contraception during treatment with Loqtorzi™ and for 4 months after the last dose.

Orphan status: Yes

New Biosimilar Products

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Wezlana™ (ustekinumab-auub) injection, for intravenous or subcutaneous use / Amgen Inc	10/31/2023	Immunological Agents	[1] For the treatment of adults and pediatric patients 6 years and older with: moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; [2] For the treatment of adults and pediatric patients 6 years and older with: active psoriatic arthritis (PsA); [3] For the treatment of adults with moderately to severely active Crohn's disease (CD); [4] For the treatment of adults with moderately to severely active ulcerative colitis.	Wezlana™ is the first approval for a biosimilar referencing blockbuster drug Stelara™ (ustekinumab). The FDA also granted an interchangeability designation. Pricing and launch date are still pending. Reference Product: Stelara™ Orphan: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Cosentyx™ (seukinumab) injection for intravenous use / Novartis Pharms Corp	10/6/2023	Immunological agents	[1] Treatment for active psoriatic arthritis (PsA) in patient 2 years of age and older; [2] Treatment for adults with active ankylosing spondylitis (AS); [3] Treatment for adults with active non-radiographic axial spondylarthritis (nr-axSpA)	Cosentyx™ IV was approved as a 125mg/mL solution in a single-dose vial. Intravenous infusion is only for use by a healthcare professional in a healthcare setting. Orphan: No
Xphozah™ (tenapanor hydrochloride) tablets Ardelix Inc	10/17/2023	Sodium hydrogen exchanger (NHE3) inhibitor	To reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy	Xphozah™ is a first-in-class phosphate absorption inhibitor for patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. Orphan: No
Combogesic™ IV (acetaminophen and ibuprofen) injection, for intravenous use / AFT Pharms LTD	10/17/2023	Analgesics	[1] For the relief of mild to moderate pain; [2] For the management of moderate to severe pain as an adjunct to opioid analgesics	Combogesic™ IV is indicated in adults where an intravenous route of administration is considered clinically necessary. It is indicated for short-term use of five days or less. It carries a black box warning for hepatotoxicity, cardiovascular risk and gastrointestinal risk. Orphan: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Qlosi™ (pilocarpine hydrochloride) ophthalmic solution / Orasis Pharmaceuticals, LTD	10/17/2023	Ophthalmic Agents	Treatment of presbyopia in adults	Qlosi™ is a preservative-free formulation of pilocarpine, an established eye care therapeutic, designed to achieve an optimal balance between efficacy, safety, and comfort. Orphan: No
Zituvio™ (sitagliptin) tablets / Zydus Worldwide DMCC	10/18/2023	Antidiabetics	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Zituvio™ shares the same indication as Januvia™. Orphan: No
Cabtreo™ (clindamycin phosphate, adapalene and benzoyl peroxide) topical gel / Bausch Health US, LLC	10/20/2023	Dermatological Agents	Topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older	Cabtreo™ is the first and only FDA-approved fixed dose, triple-combination treatment for acne and represents a new option. It is expected to be available in 1Q 2024. Orphan: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Coxanto™ (oxaprozin) capsules, for oral use/ Solubiomix, LLC	10/20/2023	Analgesics	[1] Treatment to relief signs and symptoms of Osteoarthritis (OA); [2] Treatment to relief signs and symptoms of Rheumatoid Arthritis (RA); [3] Treatment to relief signs and symptoms of Juvenile Rheumatoid Arthritis (JRA)	Coxanto™ carries a black box warning for cardiovascular thrombotic events and gastrointestinal events. Orphan: N/A
Rozlytrek™ (entrectinib) oral pellets / Genentech Inc	10/20/2023	Antineoplastics	[1] Treatment of adult patients with *ROSI*-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA approved test; [2] Treatment of adult and pediatric patients older than 1 month of age with solid tumors that: A. Have a neurotrophic tyrosine kinase (NTRK) gene fusion, as detected by an FDA approved test without a known acquired resistance mutation, B. Are metastatic or where surgical resection is likely to result in severe morbidity, and C. Have progressed following treatment or have no satisfactory alternative therapy	With the FDA approval for the new pellets dosage form available in strength of 50mg per packet, patient population was extended to pediatric patients older than 1 month of age Orphan: Yes
Zymfentra™ (infliximab-dyyb) injection, for subcutaneous use / Celltrion USA, Inc.	10/20/2023	Immunosuppre-ssants	[1] Maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously; [2] Maintenance treatment of moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously	Zymfentra™ is the first FDA-approved subcutaneous formulation of infliximab indicated as maintenance treatment only. Patients must complete an intravenous induction regimen with an infliximab product before starting Zymfentra™. Zymfentra™ is considered a biobetter of Inflectra™. Orphan: Yes

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)	Projected Launch Date
Pazopanib hydrochloride tablets 200mg	Apotex Corp; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals USA, Inc.	10/19/2023	Votrient™	Antineiplastics	[1] Renal cell carcinoma; [2] Soft tissue sarcoma	10/20/2023

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Zoryve™ (roflumast) cream / Arcutis Biotherapeutics, Inc.	Dermatological Agents	Topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older	Topical treatment of plaque psoriasis including intertriginous areas, in patients 6 years of age and older	10/5/2023
Braftovi™ (encorafenib) capsules / Array Biopharma Inc	Antineoplastics	[1] In combination with binimetinib for patients with unresectable or metastatic melanoma with BRAF V600 or C600K mutation; [2] Treatment in combination with Cetuximab for adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation	In combination with binimetinib for adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAFV 600E mutation	10/11/2023
Opdivo™ (nivolumab) injection / Bristol Myers Squibb	Antineoplastics	[1] Melanoma; [2] Non-small cell lung cancer (NSCLC); [3] Malignant Pleural Mesothelioma; [4] Renal Cell Carcinoma (RCC); [5] Classical Hodgkin Lymphoma (cHL); [6] Squamous Cell Carcinoma of the Head and Neck (SCCHN); [7] Urothelial Carcinoma; [8] Colorectal Cancer; [9] Hepatocellular Carcinoma (HCC); [10] Esophageal Cancer; [11] Gastric Cancer, Gastroesophageal Junction Cancer and Esophageal Adenocarcinoma	For the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma	10/13/2023

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Keytruda™ (pembrolizumab) injection / Merck Sharp Dohme	Antineoplastics	[1] Melanoma; [2] Non-small cell lung cancer (NSCLC); [3] Head and neck squamous cell cancer (HNSCC); [4] Classical Hodgkin lymphoma (cHL); [5] Primary mediastinal large B-cell lymphoma (PMBCL); [6] Urothelial carcinoma; [7] Microsatellite Instability–high or mismatch repair deficient cancer; [8] Gastric cancer; [9] Esophageal cancer; [10] Cervical cancer; [11] Hepatocellular carcinoma; [12] Merkel cell carcinoma; [13] Renal cell carcinoma; [14] Endometrial carcinoma; [15] Tumor mutational Burden-high cancer; [16] Cutaneous squamous cell carcinoma; [17] Triple-negative breast cancer	[1] Treatment of patients with resectable (tumors ≥ 4 or node positive) NSCLC in combination with platinum- containing chemotherapy as neoadjuvant treatment, and continued as a single agent, for adjuvant treatment after surgery	10/16/2023
Voxzogo™ (vosoritide) injection / Biomarin Pharm	Endocrine and Metabolic Agents	To increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses	To increase linear growth in pediatric patients with achondroplasia with open epiphyses	10/20/2023
Tibsovo™ (ivosidenib) tablets / Servier Pharmaceuticals	Antineoplastics	[1] Newly Diagnosed Acute Myeloid Leukemia (AML); [2] Relapsed or refractory AML; [3] Locally Advanced or Metastatic Cholangiocarcinoma	Treatment of adult patients with relapsed or refractory Myelodysplastic Syndromes (MDS)	10/24/2023
Vabysmo™ (faricimab-svoa) injection / Genentech Inc	Ophthalmic Agents	[1] Neovascular (wet) age-related macular degeneration; [2] Diabetic macular edema	Treatment of macular edema following retinal vein occlusion (RVO)	10/26/2023
Cosentyx (secukinumab) injection, for subcutaneous use / Novartis Pharms Corp	Immunological Agents	[1] Plaque psoriasis; [2] Ankylosing spondylitis; [3] Psoriatic arthritis; [4] Non-radiographic axial spondyloarthritis; [5] Enthesitis-related arthritis	Treatment of adult patients with moderate to severe hidradenitis suppurativa (HS)	10/31/2023

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Ceftobiprole medocaril / Basilea Pharmaceutica Ltd.	10/2/2023	*Staphylococcus aureus* bacteremia (SAB), including right-side infective endocarditis, acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP)	Ceftobiprole medocaril, the prodrug of the active moiety ceftobiprole, is a cephalosporin antibiotic for intravenous administration, with rapid bactericidal activity against a wide range of Gram-positive bacteria such as *Staphylococcus aureus*, including methicillin-resistant strains (MRSA), and Gram-negative bacteria. It has been designated a Qualified Infectious Disease Product. If NDA submission is accepted, a decision is expected by the FDA on the NDA in the second quarter of 2024. NDA accepted.	Moderate
Udenyca™ (pegfilgrastim-cbqv) injection / Coherus BioSciences, Inc.	10/5/2023	[1] Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia; [2] Increase in survival in patients acutely exposed to myelosuppressive doses of situation of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)	The resubmission of the Udenyca™ OnBody BLA Supplement follows the completion and satisfactory resolution of the FDA's review of inspection findings at a third-party filler, which was the only issue identified in the Complete Response Letter (CRL) the FDA issued on September 21, 2023. NDA resubmitted.	Moderate
Deuruxolitinib / Sun Pharma Industries Inc	10/6/2023	Treatment of adults with moderate to severe alopecia areata	Deuruxolitinib is a JAK1/JAK2 inhibitor that works by targeting the γc cytokine and interferon-gamma (IFN-γ) signaling pathway to reverse the hair loss in alopecia areata. Sun Pharma has submitted 8mg twice daily regimen of deuruxolitinib for FDA review. NDA accepted.	Moderate

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Cardamyst™ (etripamil) nasal spray / Milestone Pharmaceuticals Inc.	10/24/2023	Treatment of paroxysmal supraventricular tachycardia (PSVT)	Etripamil is a novel calcium channel blocker nasal spray being developed for elevated and often highly symptomatic heart-rate attacks associated with PSVT and atrial fibrillation with a rapid ventricular rate. It is designed to be a rapid-response therapy that is self-administered by the patient, without the need for direct medical oversight. NDA submitted.	High
Vadadustat / Akebia Therapeutics, Inc.	10/25/2023	Treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis	Akebia Therapeutics Inc. had resubmitted its new drug application to the FDA for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor. The FDA turned down the first NDA by the company for the drug in 2022 citing concerns about vascular access complications and liver toxicity. NDA accepted.	Moderate
Tovorafenib / Day One Biopharmaceuticals	10/30/2023	As a monotherapy in relapsed or progressive pediatric low-grade glioma	Tovorafenib is an investigational, oral, brain-penetrant, highly-selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway, which may offer an alternative for individuals with primary brain tumors or brain metastases of solid tumors. It has been granted Priority Review and has been set a Prescription Drug User Fee Act (PDUFA) for April 30, 2024. NDA accepted.	High high
Mavorixafor / X4 Pharmaceuticals	10/31/2023	Treatment of individuals aged 12 and older with Warts, Hypogammaglobulinemia, Infections and Myelokathexis (WHIM) syndrome	Mavorixafor is an investigational small-molecule antagonist of CXCR4. It is being developed as a once-daily oral therapy. It has been granted Breakthrough Therapy Designation, Fast Track Designation, and Rare Pediatric Designation in the U.S., and Orphan Drug Status. The FDA assigned a PDUFA target action date of April 30, 2024 NDA accepted.	High high

References

- *New Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/newdrugs.html.
- *Latest Generic Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/generic-approvals.html.
- *New Indications & Dosage Forms for Existing Drugs*. Drugs.com. (2023). https://www.drugs.com/new-indications.html.
- *New Drug Applications*. Drugs.com. (2023). https://www.drugs.com/new-drug-applications.html.
- *Drugs@FDA: FDA-Approved Drugs. Accessdata.FDA.gov. (2023). https://www.accessdata.fda.gov/scripts/cder/daf/.*