PHARMNOTES

May 2023

Date: 6/8/2023

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Drug Safety Alert Notification

- No drug safety communication published in May.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
ELFABRIO™ (PEGUNIGALSIDASE ALFA-IWXJ) INJECTION	CHIESI FARMACEUTICI SPA	5/9/2023

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Elfabrio™ is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease.

DOSAGE AND ADMINISTRATION
- Pretreatment with antihistamines, antipyretics, and/or corticosteroids is or may recommended depending on prior use of enzyme replacement therapy.
- Recommended dosage: 1mg/kg every 2 weeks administered as an intravenous infusion.

DOSAGE FORMS AND STRENGTHS
Injection: 20 mg/10 mL (2 mg/mL) solution in a single-dose vial.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS**
  - Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, discontinue Elfabrio™ immediately and initiate appropriate medical treatment.
- Infusion-Associated Reactions (IARs): If severe IARs occur, discontinue Elfabrio™ and initiate appropriate medical treatment.
- Membranoproliferative Glomerulonephritis: Monitor serum creatinine and urinary protein to creatinine ratio. Discontinue Elfabrio™ if glomerulonephritis is suspected, until a diagnostic evaluation can be conducted.

ADVERSE REACTIONS
- Most common adverse reactions (≥15%) are: infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

USE IN SPECIFIC POPULATIONS
- Patients with Prior Enzyme Replacement Therapy: Patients that received prior ERT are more likely to have pre-existing anti-drug antibodies (ADA) to pegunigalsidase alfa-iwxj which could be due to the ADA crossreactivity to pegunigalsidase alfa-iwxj by prior ERT. Consider monitoring clinical or pharmacodynamic responses (e.g., plasma lyso-Gb3 levels) when switching from agalsidase beta to Elfabrio™ , in patients with pre-existing ADA.

DRUG NAME	MANUFACTURER	APPROVAL DATE
VEOZAH™ (FEZOLINETANT) TABLETS	ASTELLAS PHARMA US, INC.	5/12/2023

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Veozah™ is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

DOSAGE AND ADMINISTRATION
- Perform baseline bloodwork to evaluate for hepatic function and injury [including serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), and serum bilirubin (total and direct)] before initiating treatment with Veozah™.
- Recommended dosage: 45mg orally once daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 45 mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known cirrhosis
- Severe renal impairment or end-stage renal disease
- Concomitant use with CYP1A2 inhibitors

WARNINGS AND PRECAUTIONS
- Hepatic Transaminase Elevation: Elevations in serum transaminase concentrations greater than three times the upper limit of normal (ULN) occurred in the clinical trials. Perform bloodwork prior to initiation of Veozah™ to evaluate for hepatic function and injury. Do not start therapy if serum transaminase concentration is equal to or exceeds two times the ULN. Perform follow-up evaluations of hepatic transaminase concentration at 3 months, 6 months, and 9 months after initiation of therapy.

ADVERSE REACTIONS
- The most common adverse reactions with Veozah™ [at least 2% in Veozah™ 45 mg and greater than placebo] are: abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.

USE IN SPECIFIC POPULATIONS
- Renal Impairment: Veozah™ is contraindicated in individuals with severe renal impairment or end-stage renal disease. No dose adjustment of Veozah™ is recommended for individuals with mild or moderate renal impairment.
- Hepatic Impairment: Child-Pugh Class A or B hepatic impairment increased the exposure of Veozah™. Veozah™ has not been studied in individuals with Child-Pugh Class C hepatic impairment.. Veozah™ is contraindicated in individuals with cirrhosis.

DRUG NAME	MANUFACTURER	APPROVAL DATE
MIEBO™ (PERFLUOROHEXYLOCTANE) OPHTHALMIC SOLUTION	BAUSCH AND LOMB INC	5/18/2023

THERAPEUTIC CLASS
Ophthalmic agents

FDA-APPROVED INDICATION(S)
Miebo™ is is a semifluorinated alkane indicated for treatment of the signs and symptoms of dry eye disease

DOSAGE AND ADMINISTRATION
- Instill one drop four times daily into each eye

DOSAGE FORMS AND STRENGTHS
Ophthalmic solution: 100% perfluorohexyloctane.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

ADVERSE REACTIONS
- Most common ocular adverse reaction was blurred vision. Blurred vision was reported in less than 4% of individuals.

DRUG NAME	MANUFACTURER	APPROVAL DATE
EPKINLY™ (EPCORITAMAB-BYSP) INJECTION	5/19/2023	GENMAB US, INC.

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Epkinly™ is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

DOSAGE AND ADMINISTRATION
- For subcutaneous injection only.
- Administer in 28-days cycles until disease progression or unacceptable toxicity:

Cycle 1 Day 1: Step-up dose 1 of 0.16mg
Cycle 1 Day 8: Step-up dose 2 of 0.8mg
Cycle 1 Day 15: First full dose of 48mg
Cycles 2 and 3 Days 1, 8, 15 and 22: 48mg
Cycles 4 to 9 Days 1 and 15: 48mg
Cycle 10 and beyond Day 1: 48mg

- Patients should be hospitalized for 24 hours after administration of the Cycle 1 Day 15 dosage of 48 mg.

DOSAGE FORMS AND STRENGTHS
Injection: 4 mg/0.8 mL in a single-dose vial. Dilute prior to use; Injection: 48 mg/0.8 mL in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: CYTOKINE RELEASE SYNDROME AND IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME**
  - Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving Epkinly™. Initiate treatment with the Epkinly™ step-up dosing schedule to reduce the incidence and severity of CRS. Withhold Epkinly™ until CRS resolves or permanently discontinue based on severity.
  - Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), including life-threatening and fatal reactions, can occur with Epkinly™. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold Epkinly™ until ICANS resolves or permanently discontinue based on severity.
- Infections: Can cause serious or fatal infections. Monitor patients for signs or symptoms of infection, including opportunistic infections, and treat appropriately.
- Cytopenias: Monitor complete blood cell counts during treatment
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

ADVERSE REACTIONS
- The most common (≥ 20%) adverse reactions are cytokine release syndrome, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) are decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on the mechanism of action, Epkinly™ may cause fetal harm when administered to a pregnant woman.
- Lactation: advise women not to breastfeed during treatment with Epkinly™ and for 4 months after the last dose
- Females and Males of Reproductive Potential: Verify pregnancy status in females of reproductive potential prior to initiating Epkinly™. Advise females of reproductive potential to use effective contraception during treatment with Epkinly™ and for 4 months after the last dose.

Orphan status: Yes

DRUG NAME	MANUFACTURER	APPROVAL DATE
XACDURO™ (SULBACTAM AND DURLOBACTAM) INJECTION	ENTASIS THERAPEUTICS INC.	5/23/2023

THERAPEUTIC CLASS
Antibacterials

FDA-APPROVED INDICATION(S)
Xacduro™ is a co-packaged product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, a beta lactamase inhibitor, indicated in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

DOSAGE AND ADMINISTRATION
- Administer Xacduro™ (1 g of sulbactam, 1 g of durlobactam) every 6 hours by intravenous (IV) infusion over 3 hours in patients with creatinine clearance (CLcr) of 45 to 129 mL/min.
- Dosing regimen adjustments are recommended for CLcr less than 45 mL/min and CLcr greater than or equal to 130 mL/min.

DOSAGE FORMS AND STRENGTHS
Co-packaged kit containing the following two components as sterile powders for reconstitution: 1 clear single-dose vial of sulbactam for injection 1 g and 2 amber single-dose vials of durlobactam for injection 0.5 g

SAFETY PROFILE

CONTRAINDICATIONS
- Known history of severe hypersensitivity to the components of Xacduro™ (sulbactam and durlobactam), or other beta-lactam antibacterial drugs.

WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported with beta-lactam antibacterial drugs. Hypersensitivity was observed in patients treated with Xacduro™. If an allergic reaction occurs, discontinue Xacduro™.
- *Clostridioides difficile*-Associated Diarrhea (CDAD): CDAD has been reported with nearly all systemic antibacterial agents, including Xacduro™. Evaluate if diarrhea occurs.

ADVERSE REACTIONS
- The most common adverse reactions (incidence > 10%) were liver test abnormalities, diarrhea, anemia, and hypokalemia.

DRUG INTERACTIONS
- Organic Anion Transporter 1 (OAT1) Inhibitors: Concomitant administration with OAT1 inhibitors may increase plasma concentrations of Xacduro™. Concomitant administration is not recommended.

USE IN SPECIFIC POPULATIONS
- Renal Impairment: Adjustments to the Xacduro™ dosing regimen are required in patients with CLcr less than 45 mL/min. In patients requiring HD, complete HD at the latest possible time before the start of Xacduro™ dosing. Dosage adjustment of Xacduro™ is required in patients with CLcr 130 mL/min or greater. Monitor renal function regularly and adjust the dosage of Xacduro™ accordingly as renal function may change during the course of therapy.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
POSLUMA™ (FLOTUFOLASTAT F 18) INJECTION	BLUE EARTH DIAGNOSTICS LTD.	5/25/2023

THERAPEUTIC CLASS
Diagnostic agents

FDA-APPROVED INDICATION(S)
Posluma™ is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

DOSAGE AND ADMINISTRATION
- Recommended amount of radioactivity of Posluma™ is 296 MBq (8 mCi) administered as an intravenous bolus injection.
- Initiate imaging approximately 60 minutes after administration. Scanning should start from mid-thigh and proceed to base of skull.

DOSAGE FORMS AND STRENGTHS
Injection: 296 MBq/mL to 5,846 MBq/mL (8 mCi/mL to 158 mCi/mL) as flotufolastat F 18 gallium in approximately 25 mL at end of synthesis in a multiple-dose vial

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Risk of Image Misinterpretation: Image interpretation errors can occur with Posluma™ imaging. Interpretation of Posluma™ PET may differ depending on imaging readers in patients with suspected recurrence of prostate cancer. Consider multidisciplinary consultation and histopathological confirmation.
- Radiation risk: Posluma™ contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

ADVERSE REACTIONS
- The most common adverse reactions (≥0.4%) are diarrhea, blood pressure increase, and injection site pain.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Not indicated for use in females. Radioactive drugs, including Posluma™, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose.

DRUG NAME	MANUFACTURER	APPROVAL DATE
PAXLOVID™ (NIRMATRELVIR AND RITONAVIR) TABLETS	PFIZER INC.	5/25/2023

THERAPEUTIC CLASS
Antivirals

FDA-APPROVED INDICATION(S)
Paxlovid™ which includes nirmatrelvir, a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

DOSAGE AND ADMINISTRATION
- Initiate Paxlovid™ treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
- Administer orally with or without food.
- Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all 3 tablets taken together twice daily for 5 days.

DOSAGE FORMS AND STRENGTHS
Tablets: nirmatrelvir 150 mg
Tablets: ritonavir 100 mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID**
  - Paxlovid™ includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life-threatening, or fatal events.
  - Prior to prescribing Paxlovid™: 1) Review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like Paxlovid™ and 2) Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring.

WARNINGS AND PRECAUTIONS (CONT.)
- **BLACK BOX WARNING (cont.):** Consider the benefit of Paxlovid™ treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed.
- The concomitant use of Paxlovid™ and certain other drugs may result in potentially significant drug interactions. Consult the Full Prescribing Information prior to and during treatment for potential drug interactions.
- Hypersensitivity Reactions: Anaphylaxis, serious skin reactions (including toxic epidermal necrolysis and Stevens-Johnson syndrome), and other hypersensitivity reactions have been reported with Paxlovid™. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue Paxlovid™ and initiate appropriate medications and/or supportive care.
- Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir.
- HIV-1 Drug Resistance: Paxlovid™ use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥1% and greater incidence than in the placebo group) are dysgeusia and diarrhea.

Continues on the next slide.

DRUG NAME	MANUFACTURER	APPROVAL DATE
PAXLOVID™ (NIRMATRELVIR AND RITONAVIR) TABLETS	PFIZER INC.	5/25/2023

THERAPEUTIC CLASS
Antivirals

FDA-APPROVED INDICATION(S)
Paxlovid™ which includes nirmatrelvir, a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

DOSAGE AND ADMINISTRATION
- Initiate Paxlovid™ treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
- Administer orally with or without food.
- Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all 3 tablets taken together twice daily for 5 days.

DOSAGE FORMS AND STRENGTHS
Tablets: nirmatrelvir 150 mg
Tablets: ritonavir 100 mg (3)

Orphan status: No

SAFETY PROFILE

DRUG INTERACTIONS
- Co-administration of Paxlovid™ can alter the plasma concentrations of other drugs and vice versa. Consider the potential for drug interactions prior to and during Paxlovid™ therapy and review concomitant medications during Paxlovid™ therapy.

USE IN SPECIFIC POPULATIONS
- Females and Males of Reproductive Potential: Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception.
- Renal Impairment: Reduce the Paxlovid™ dosage in patients with moderate renal impairment. Not recommended for use in patients with severe renal impairment or patients with end stage renal disease receiving dialysis until more data is available. Providers should counsel patients about renal dosing instructions.
- Hepatic Impairment: No pharmacokinetic or safety data are available regarding the use of nirmatrelvir or ritonavir in subjects with severe hepatic impairment, therefore, Paxlovid™ is not recommended for use in patients with severe hepatic impairment.

DRUG NAME	MANUFACTURER	APPROVAL DATE
INPEFA™ (SOTAGLIFLOZIN) TABLETS	LEXICON PHARMACEUTICALS INC	5/26/2023

THERAPEUTIC CLASS
Antidiabetics

FDA-APPROVED INDICATION(S)
Inpefa™ is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors.

DOSAGE AND ADMINISTRATION
- Correct volume status before starting Inpefa™ at 200 mg daily and titrate to 400 mg as tolerated.
- In patients with decompensated heart failure, begin dosing when patients are hemodynamically stable.
- Withhold Inpefa™ at least 3 days, if possible, prior to major surgery or procedures associated with prolonged fasting.

DOSAGE FORMS AND STRENGTHS
Tablets: 200 mg and 400 mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- History of serious hypersensitivity reaction to Inpefa™.

WARNINGS AND PRECAUTIONS
- Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis: Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue Inpefa™ if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting.
- Volume Depletion: Before initiating, correct volume status. Monitor for signs and symptoms of hypotension during therapy.
- Urosepsis and Pyelonephritis: Monitor for signs and symptoms during therapy and treat promptly.
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Lower dose of insulin or insulin secretagogue may be required.
- Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Monitor for pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. Discontinue Inpefa™ and treat urgently.
- Genital Mycotic Infections: Monitor and treat as appropriate.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥ 5%) are urinary tract infection, volume depletion, diarrhea, and hypoglycemia.

DRUG INTERACTIONS
- Digoxin: Monitor digoxin levels.
- Uridine 5'-diphospho-glucuronosyltransferase Inducers (e.g., rifampin): Sotagliflozin exposure is reduced. Consider monitoring of clinical status.
- Lithium: Monitor serum lithium concentrations.

USE IN SPECIFIC POPULATIONS
Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters.
Lactation: Inpefa™ is not recommended when breastfeeding.
Geriatrics: Higher incidence of adverse reactions related to volume depletion.
Renal Impairment: Higher incidence of adverse reactions related to volume depletion.

New Biosimilar Products

Drug Name and Manufacturer	Date	Therapeutic Class	Additional Information
Yuflyma™ (adalimumab-aaty) injection / Celltrion, Inc.	5/23/2023	Analgesics – Anti-inflammatory	Reference Product: Humira™ The FDA has approved Yuflyma™, a high concentration and citrate-free formulation of adalimumab biosimilar. It has been approved for eight indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis and hidradenitis suppurativa. The drug features a prefilled syringe and autoinjector administration. It will be available in the 40mg/0.4mL dosage. The company will seek an interchangeability designation from the FDA, which is tentatively expected in the fourth quarter of 2024. Orphan status: No Controlled substance: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Lumryz™ (soidum oxybate) extended-release oral suspension / Avadel Pharmaceuticals	5/1/2023	Wakefulness Promoting Agents	Treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy	Lumryz™ is the first and only FDA-approved once-at-bedtime oxybate for people living with narcolepsy. Orphan: Yes Controlled Substance: CIII
Motpoly™ XR (lacosamide) extended-release capsules / Acute Pharmaceuticals	5/4/2023	Anticonvulsants	Treatment of partial-onset seizures in adults in pediatric patients weighing at least 50kg	Motpoly™ XR is an extended-release formulation of lacosamide. The efficacy is based on the relative bioavailability of Motpoly™ XR compared to immediate-release lacosamide in healthy adults. Orphan: No Controlled Substance: CV
Mydcombi™ (tropicamide and phenylephrine hydrochloride) ophthalmic spray / Eyenovia, Inc.	5/5/2023	Ophthalmic agents	To induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired	Mydcombi™ is a fixed-dose combination of dilating medications that dispenses the drugs in microdoses horizontally as a spray with the push of a button. Orphan: No
Zolpidem tartrate capsules / Almatica Pharma LLC	5/9/2023	Sleep disorder agents	Short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age	Zolpidem capsules are only available in 7.5mg strength. It is recommended to start with another zolpidem tartrate immediate release product for the 5mg and 10mg dosage. Orphan: No Controlled Substance: CIII

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Opvee™ (nalmefene) nasal spray / Opiant Pharmaceuticals Inc.	5/22/2023	Opioid reversal agents	Emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older as manifested by respiratory and/or central nervous system depression	Opvee™ is a new formulation for the drug nalmefene, which was first approved as an injection. Opvee™ is similar to naloxone as both work by blocking the effects of opioids in the brain and restoring normal breathing and blood pressure in people who have recently overdosed. Orphan: No
Brixadi™ (buprenorphine) extended-release injection / Braeburn Inc.	5/23/2023	Opioid dependence	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine	Brixadi™ is available in two formulations: weekly injection and monthly injection. Doses of the weekly injection cannot be combined to yield an equivalent monthly dose. Orphan: No Controlled Substance: CIII
Vevye™ (cyclosporine) ophthalmic solution / Alliance Medical Products, Inc.	5/30/2023	Ophthalmic agents	Treatment of the signs and symptoms of the dry eye disease	Vevye™ is a new formulation of cyclosporine with a twice-daily dosing. Orphan: No

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)	Projected Launch Date
Methsuximide capsules 300mg	Novitium Pharma LLC	5/1/2023	Celontin™	Anticonvulsants	Seizures	Launched
Obeticholic acid tablets 5mg and 10mg	Apotex Corp.; Lupin Pharmaceuticals, Inc.; MSM Laboratories Private Limited	5/30/2023	Ocaliva™	Genetic, Enzyme, or Protein Disorder: Replacement, Modifiers, Treatment	Primary biliary cholangitis	9/1/2031
Diazepam rectal gel 10mg/2mL (5mg/mL) and 20mg/4mL (5mg/mL)	Novel Laboratories, Inc.	5/30/2023	Diastat AcuDial™	Anticonvulsants	Seizures	Unknown

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Farxiga™ (dapagliflozin) tablets / AstraZeneca	Antidiabetics	[1] Type 2 diabetes mellitus; [2] Type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors; [3] Chronic kidney disease; [4] Heart failure with reduced ejection fraction	To reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure	5/8/2023
Rexulti™ (brexpiprazole) tablets / Otsuka Pharmaceutical, Co. Ltd.	Antipsychotics	[1] Schizophrenia; [2] Agitation associated with dementia due to Alzheimer's disease	As an adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults	5/10/2023
Caldolor™ (ibuprofen) injection / Cumberland Pharmaceuticals Inc.	Analgesics	[1] Mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics in adults and pediatric patients aged 6 months and older; [2] Fever in adults and pediatric patients aged 6 months and older	[1] Mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics in adults and pediatric patients aged 3 months and older; [2] Fever in adults and pediatric patients aged 3 months and older	5/15/2023
Rinvoq™ (upadacitinib) extended-release tablets / AbbVie	Analgesics	[1] Active rheumatoid arthritis; [2] Active psoriatic arthritis; [3] Atopic dermatitis; [4] Active ulcerative colitis; [5] Active ankylosing spondylitis; [6] Active non-radiographic axial spondyloarthritis	Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers	5/18/2023

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Ayvakit™ (avapritinib) tablets / Blueprint Medicines Corp.	Antineoplastics	[1] Gastrointestinal stromal tumor; [2] Advanced systemic mastocytosis	Treatment of adult patients with indolent systemic mastocytosis	5/22/2023
Injectafer™ (ferric carboxymaltose) injection / American Regent	Hematopoietic Agents	[1] Iron deficiency anemia in: adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron or adult patients who have non-dialysis dependent chronic kidney disease	Treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity	5/31/2023

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Rivoceranib and camrelizumab / Elevar Therapeutics, Inc.	5/17/2023	First-line treatment option for unresectable hepatocellular carcinoma	The Phase 3 CARES 310 study, evaluating rivoceranib plus camrelizumab versus sorafenib, demonstrated statistically significant and clinically meaningful prolonged overall survival and progression-free survival, and improved overall response rate versus sorafenib, a standard first-line treatment for uHCC. NDA submitted.	High high
STS101 / Satsuma Pharmaceuticals, Inc.	5/18/2023	Acute treatment of migraine	STS101 is designed to be easy-to-carry, quick and easy to self-administer within seconds without need for involved administration procedures and to rapidly achieve high drug plasma levels believed necessary for robust efficacy and to be below those levels associated with adverse events such as nausea and vomiting. NDA accepted.	Moderate

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Lumisight™ Optical Imaging Agent (pegulicianine) / Lumicell, Inc.	5/22/2023	For fluorescence imaging of the lumpectomy cavity	Lumisight™ (pegulicianine) is an optical imaging agent in development for the detection of residual cancerous tissue during breast cancer surgery. It is used with the Lumicell Direct Visualization System (DVS) which is a hand-held imaging probe that enables the surgeon to scan inside the breast cavity to illuminate and find activated Lumisght™ in any residual cancer. It was granted Fast Track designation. NDA accepted.	High
Vonoprazan / Phathom Pharmaceuticals, Inc.	5/23/2023	Treatment of erosive gastroesophageal reflux disease (GERD)	Vonoprazan is a novel first-in-class potassium-competitive acid blocker. The resubmission of this NDA is a response to the Complete Response Letter issued by the FDA in February 2023 relating to the specifications and controls for an impurity (N-nitroso-vonoprazan). If the NDA is approved, a combined U.S. commercial launch for the erosive GERD and *H. pylori* indications is planned for the fourth quarter of 2023. NDA resubmitted.	Moderate

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Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Lifileucel / Iovance Biotherapeutics, Inc.	5/26/2023	Treatment of advanced unresectable or metastatic melanoma in patients who have progressed on or after prior anti-PD-1/L1 therapy and targeted therapy	Lifileucel is a novel polyclonal tumor infiltrating lymphocyte (TIL). It has been granted Priority Review and has been assigned a Prescription Drug User Fee Act (PDUFA) of November 25, 2023. BLA submitted.	High
Macitentan and tadalafil / Janssen Pharmaceuticals Co.	5/30/2023	Long-term treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adult patients with WHO functional class II-III	Macitentan and tadalafil is the first investigational, single tablet combination therapy that combines the endothelin receptor antagonist (macitentan) and the phosphodiesterase type 5 inhibitor (tadalafil) for once daily administration. NDA submitted.	Moderate
Repotrectinib / Bristol Myers Squibb	5/30/2023	Treatment of patients with *ROS1*-positive locally advanced or metastatic non-small cell lung cancer	Repotrectinib is a next-generation tyrosine kinase inhibitor (TKI). The FDA granted the application Priority Review and assigne a PDUFA goal date of November 27, 2023. NDA accepted.	High

References

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