PHARMNOTES

December 2022

Date: 1/10/2023

Table of Contents

Drug Safety Alert Notification

- No drug safety alert published in December.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
REZLIDHIA™ (OLUTASIDENIB) CAPSULES	RIGEL PHARMS INC	12/1/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Rezlidhia™ is an isocitrate dehydrogenase-1 (IDH1) indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
- Select patients based on the presence of IDH1 mutations in blood or bone marrow.
- Recommended dosage is 150mg taken orally twice daily until disease progression or unacceptable toxicity.
- Take on an empty stomach at least 1 hour before or 2 hours after a meal.
- For patients without disease progression or unacceptable toxicity, treat for a minimum of 6 months to allow time for clinical response.

DOSAGE FORMS AND STRENGTHS
Capsules: 150mg

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Hepatotoxicity: Monitor liver function tests during treatment with Rezlidhia™. If hepatotoxicity occurs, interrupt and reduce or discontinue Rezlidhia™.

ADVERSE REACTIONS
- The most common (≥20%) adverse reactions, including laboratory abnormalities, are aspartate aminotransferase increased, alanine aminotransferase increased, potassium decreased, sodium decreased, alkaline phosphatase increased, nausea, creatinine increased, fatigue/malaise, arthralgia, constipation, lymphocytes increased, bilirubin increased, leukocytosis, uric acid increased, dyspnea, pyrexia, rash, lipase increased, mucositis, diarrhea and transaminitis.

DRUG INTERACTIONS
- Strong or Moderate CYP3A Inducers: Avoid concomitant use.
- Sensitive CYP3A Substrates: Avoid concomitant use. Monitor if unavoidable.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on animal embryo-fetal toxicity studies, Rezlidhia™ may cause fetal harm when administered to a pregnant woman.
- Lactation: Because many drugs are excreted in human milk, and due to the potential for adverse reactions in a breastfed child, advise women not to breastfeed during treatment with Rezlidhia™ and for 2 weeks after the last dose.
- Pediatric Use: The safety and effectiveness of Rezlidhia™ have not been established in pediatric patients.
- Geriatric Use: No overall differences in effectiveness were observed between patients 65 years and older and younger patients. Compared to patients younger than 65 years of age, an increase in incidence of hepatotoxicity and hypertension was observed in patients ≥65 years of age.
- Renal Impairment: The recommended dosage of Rezlidhia™ has not been established in patients with severe renal impairment (CLcr 15 to 29 mL/min as estimated by Cockcroft-Gault), kidney failure (CLcr <15 mL/min, as estimated by Cockcroft-Gault), and patients on dialysis.
- Hepatic Impairment: In patients with mild or moderate hepatic impairment, closely monitor for increased probability of differentiation syndrome The recommended dosage of Rezlidhia™ has not been established in patients with severe hepatic impairment (total bilirubin > 3 times ULN with any AST).

DRUG NAME	MANUFACTURER	APPROVAL DATE
KRAZATI™ (ADAGRASIB) TABLETS	MIRATI THERAPEUTICS INC.	12/12/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Krazati™ is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

DOSAGE AND ADMINISTRATION
- Select patients for treatment of locally advanced or metastatic NSCLC with Krazati™ based on the presence of KRAS G12C mutation in plasma or tumor specimens. If no mutation is detected in a plasma specimen, test tumor tissue.
- The recommended dosage of KRAZATI is 600 mg orally twice daily until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Gastrointestinal Adverse Reactions: Monitor patients for diarrhea, nausea and vomiting and provide supportive care as needed. Withhold, reduce the dose or permanently discontinue based on severity.
- QTc Interval Prolongation: Avoid concomitant use of Krazati™ with other products with a known potential to prolong the QTc interval. Monitor ECG and electrolytes in patients at risk, and in patients taking medications known to prolong the QT interval. Withhold, reduce the dose, or permanently discontinue based on severity.
- Hepatotoxicity: Monitor liver laboratory tests prior to the start of Krazati™ and monthly for 3 months after and as clinically indicated. Reduce the dose, withhold, or permanently discontinue based on severity.
- Interstitial Lung Disease / Pneumonitis: Monitor for new or worsening respiratory symptoms. Withhold Krazati™ for suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

ADVERSE REACTIONS
- The most common (≥ 25%) adverse reactions were nausea, diarrhea, vomiting, fatigue, musculoskeletal pain, hepatotoxicity, renal impairment, edema, dyspnea, and decreased appetite.
- The most common Grade 3 or 4 (≥ 2%) laboratory abnormalities were decreased lymphocytes, decreased hemoglobin, increased alanine aminotransferase, increased aspartate aminotransferase, hypokalemia, hyponatremia, increased lipase, decreased leukocytes, decreased neutrophils and increased alkaline phosphatase.

DRUG INTERACTIONS
- Strong CYP3A4 Inducers: Avoid concomitant use.
- Strong CYP3A4 Inhibitors: Avoid concomitant use until adagrasib concentrations have reached steady state.
- Sensitive CYP3A4 Substrates: Avoid concomitant use with sensitive CYP3A4 substrates.
- Sensitive CYP2C9 or CYP2D6 Substrates or P-gp Substrates: Avoid concomitant use with sensitive CYP2C9 or CYP2D6 substrates or P-gp substrates where minimal concentration changes may lead to serious adverse reactions.
- Drugs that Prolong QT Interval: Avoid concomitant use with Krazati™.

DRUG NAME	MANUFACTURER	APPROVAL DATE
KRAZATI™ (ADAGRASIB) TABLETS	MIRATI THERAPEUTICS INC.	12/12/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Krazati™ is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

DOSAGE AND ADMINISTRATION
- Select patients for treatment of locally advanced or metastatic NSCLC with Krazati™ based on the presence of KRAS G12C mutation in plasma or tumor specimens. If no mutation is detected in a plasma specimen, test tumor tissue.
- The recommended dosage of KRAZATI is 600 mg orally twice daily until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg

Orphan status: Yes

SAFETY PROFILE (cont.)

USE IN SPECIFIC POPULATIONS
- Lactation: Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with Krazati™ and for 1 week after the last dose.
- Females and Males of Reproductive Potential: Based on findings from animal studies, Krazati™ may impair fertility in females and males of reproductive potential.
- Pediatric Use: The safety and effectiveness of Krazati™ has not been established in pediatric patients.
- Geriatric Use: No overall differences in safety or effectiveness were observed between older and younger patients.

DRUG NAME

SUNLENCA™ (LENACAPAVIR) TABLETS / INJECTION

MANUFACTURER

GILEAD SCIENCES

APPROVAL DATE

12/22/2022

THERAPEUTIC CLASS

Antivirals

FDA-APPROVED INDICATION(S)

Sunlenca™, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSAGE AND ADMINISTRATION

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Initiation Option 2	
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	300 mg orally (1 x 300 mg tablet)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance	
927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/-2 weeks.	

DOSAGE FORMS AND STRENGTHS

Tablets: 300mg
Injection: 463.5mg/1.5mL in single-dose vials

SAFETY PROFILE

CONTRAINDICATIONS

- Concomitant administration of Sunlenca™ is contraindicated with strong CYP3A inducers.

WARNINGS AND PRECAUTIONS

- Immune Reconstitution Syndrome: May necessitate further evaluation and treatment.
- Residual concentrations of lenacapavir may remain in systemic circulation for up to 12 months or longer. Counsel patients regarding the dosing schedule; non-adherence could lead to loss of virologic response and development of resistance.
- May increase exposure and risk of adverse reactions to drugs primarily metabolized by CYP3A initiated within 9 months after the last subcutaneous dose of Sunlenca™.
- If discontinued, initiate an alternative, fully suppressive antiretroviral regimen where possible no later than 28 weeks after the final injection of Sunlenca™. If virologic failure occurs, switch to an alternative regimen if possible.
- Injection site reactions may occur, and nodules and indurations may be persistent.

ADVERSE REACTIONS

- Most common adverse reactions (incidence greater than or equal to 3%, all grades) are nausea and injection site reactions.

DRUG INTERACTIONS

- Consult the Full Prescribing Information prior to and during treatment for important drug interactions.

USE IN SPECIFIC POPULATION

- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to Sunlenca™ during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.
- Lactation: Because of the potential for 1) HIV transmission (in HIV-negative infants); 2) developing viral resistance (in HIV-positive infants); and 3) adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving Sunlenca™.
- Pediatric Use: Safety and effectiveness has not been established in pediatric population.
- Renal Impairment: Sunlenca™ has not been studied in patients with end-stage renal disease.
- Hepatic Impairment: Sunlenca™ has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
LUNSUMIO™ (MOSUNETUZUMAB-AXGB) INJECTION	GENENTECH INC.	12/22/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Lunsumio™ is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

DOSAGE AND ADMINISTRATION
- Premedicate to reduce the risk of cytokine release syndrome and infusion-related reactions.
- Administer only as an intravenous infusion.
- Recommended dosage:
  - Cycle 1 Day 1 – 1mg
  - Cycle 1 Day 8 – 2mg
  - Cycle 1 Day 15 – 60mg
  - Cycle 2 Day 1 – 60mg
  - Cycle 3+ Day 1 – 30mg

DOSAGE FORMS AND STRENGTHS
Injection:
- 1mg/mL solution in a single-dose vial
- 30mg/30mL solution in a single-dose vial

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Neurologic Toxicity: Can cause serious neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Monitor patients for signs and symptoms of neurologic toxicity during treatment; withhold or permanently discontinue based on severity.
- Infections: Can cause serious or fatal infections. Monitor patients for signs and symptoms of infection, including opportunistic infections, and treat as needed.
- Cytopenias: Monitor complete blood cell counts during treatment.
- Tumor Flare: Can cause serious tumor flare reactions. Monitor patients at risk for complications of tumor flare.
- 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 adverse reactions (≥ 20%) are cytokine release syndrome, fatigue, rash, pyrexia, and headache.
- The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) are decreased lymphocyte count, decreased phosphate, increased glucose, decreased neutrophil count, increased uric acid, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on the mechanism of action, Lunsumio™ may cause fetal harm when administered to a pregnant woman.
- Lactation: Because human IgG is present in human milk, and there is potential for mosunetuzumab-axgb absorption leading to B-cell depletion, advise women not to breastfeed during treatment with Lunsumio™ and for 3 months after the last dose.
- Females and Males of Reproductive Potential: Verify pregnancy status in females of reproductive potential prior to initiating Lunsumio™. Advise females of reproductive potential to use effective contraception during treatment with Lunsumio™ and for 3 months after the last dose.
- Pediatric Use: The safety and efficacy of Lunsumio™ have not been established in pediatric patients.

DRUG NAME	MANUFACTURER	APPROVAL DATE
XENOVIEW™ (XENON XE 129 HYERPOLARIZED) FOR ORAL INHALATION	POLAREAN INC	12/23/2022

THERAPEUTIC CLASS
Diagnostic products

FDA-APPROVED INDICATION(S)
Xenoview™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

DOSAGE AND ADMINISTRATION
- The recommended target dose of Xenoview™ for adult and pediatric patients aged 12 years and older is 75 mL to 100 mL Dose Equivalent (DE) of hyperpolarized xenon Xe 129 by oral inhalation of the entire contents of one Xenoview™ Dose Delivery Bag.
- Administer dose within 5 minutes of DE measurement.
- Initiate imaging immediately after inhalation.

DOSAGE FORMS AND STRENGTHS
Clear, colorless, odorless gas contained in a 1,000 mL Xenoview™ Dose Delivery Bag. The bag contains at least 75 mL DE of hyperpolarized xenon Xe 129 in a volume of 250 mL to 750 mL total xenon.

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with Xenoview™ inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to Xenoview™ inhalation, and resume oxygen inhalation immediately following the imaging breath hold.
- Risk of Transient Hypoxia: Inhalation of an anoxic gas such as Xenoview™ may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen saturation and symptoms of hypoxemia and treat as clinically indicated.

ADVERSE REACTIONS
- The adverse reactions in efficacy trials were oropharyngeal pain, headache, and dizziness.

USE IN SPECIFIC POPULATIONS
- Pediatric Use: Although supportive safety data are available for pediatric patients 6 years to less than 12 years of age, use of Xenoview™ is not approved in this age group because the age-appropriate dose of Xenoview™ cannot be accurately administered. Safety and effectiveness of Xenoview™ have not been established in pediatric patients less than 6 years of age.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
NEXOBRID™ (ANACAULASE-BCDB) FOR TOPICAL GEL	MEDIWOUND, LTD	12/28/2022

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Nexobrid™ contains proteolytic enzymes and is indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns.

DOSAGE AND ADMINISTRATION
- For topical use only.
- May be applied in up to two applications of 4 hours each.
- A first application may be applied to an area of up to 15% body surface area (BSA).
- A second application may be applied 24 hours later. The total treated area for both applications must not exceed 20% BSA.
- Prepare Nexobrid™ at patient's bedside within 15 minutes of intended application.

DOSAGE FORMS AND STRENGTHS
For topical gel: 8.8%

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any of the other components.
- Known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.

WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, have been reported with post-marketing use of anacaulase-bcdb. If a hypersensitivity reaction occurs, remove Nexobrid™ (if applicable) and initiate appropriate therapy.
- Pain: Manage pain as appropriate for an extensive dressing change of burn wounds. At least 15 minutes prior to Nexobrid™-related procedures ensure adequate pain control measures are in place.
- Proteolytic Injury to Non-Target Tissues: Nexobrid™ is not recommended for treatment of burn wounds where medical devices or vital structures could become exposed during eschar removal. Protect any open wounds with skin protectant ointments or ointment gauze to prevent possible exposure to Nexobrid™.
- Coagulopathy: Avoid use of Nexobrid™ in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.

ADVERSE REACTIONS
- The most common adverse reactions (>10%) were pruritus and pyrexia.

USE IN SPECIFIC POPULATIONS
- Pediatric Use: The safety and effectiveness of Nexobrid™ in pediatric patients have not been established.

DRUG NAME	MANUFACTURER	APPROVAL DATE
BRIUMVI™ (UBLITUXIMAB-XIIY) INJECTION FOR INTRAVENOUS USE	TG THERAPEUTICS INC.	12/28/2022

THERAPEUTIC CLASS
Psychotherapeutic and Neurological Agents

FDA-APPROVED INDICATION(S)
Briumvi™ is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
- Hepatitis B virus screening and quantitative serum immunoglobulin screening are required before first dose.
- Pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine (e.g., diphenhydramine) prior to each infusion.
- Administer Briumvi™ by intravenous infusion.
- First infusion: 150 mg intravenous infusion
- Second infusion: 450 mg intravenous infusion two weeks after the first infusion
- Subsequent infusions: 450 mg intravenous infusion 24 weeks after the first infusion and every 24 weeks thereafter.

DOSAGE FORMS AND STRENGTHS
Injection: 150 mg/6 mL (25 mg/mL) in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS
- Active hepatitis B virus infection
- History of life-threatening infusion reaction to Briumvi™

WARNINGS AND PRECAUTIONS
- Infusion Reactions: Management recommendations for infusion reactions depend on the type and severity of the reaction. Permanently discontinue Briumvi™ if a life-threatening or disabling infusion reaction occurs.
- Infections: Serious, including life-threatening and fatal infections, have occurred. Delay Briumvi™ administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment with Briumvi™ and after discontinuation, until B-cell repletion.
- Reduction in Immunoglobulins: Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with Briumvi™, until B-cell repletion, and especially when recurrent serious infections are suspected. Consider discontinuing Briumvi™ in patients with serious opportunistic or recurrent serious infections, and if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
- 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 at least 6 months after stopping Briumvi™.

ADVERSE REACTIONS
- The most common adverse reactions (≥10%) were infusion reactions and upper respiratory tract infections.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Although there are no data on ublituximab-xiiy, monoclonal antibodies can be actively transported across the placenta, and Briumvi™ may cause immunosuppression in the in-utero exposed infant.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BRIUMVI and any potential adverse effects on the breastfed infant from BRIUMVI or from the underlying maternal condition.
- Females and Males with Reproductive Potential: Pregnancy testing is recommended for females of reproductive potential prior to each infusion. Females of reproductive potential should use effective contraception while receiving Briumvi™ and for 6 months after the last dose of Briumvi™.
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Orphan status: No

New Biosimilar Products

Drug Name and Manufacturer	Date	Therapeutic Class	Additional Information
Idacio™ (adalimumab-aacf) injection for subcutaneous use / Fresenius Kabi USA	12/13/2022	Analgesics – Anti-inflammatory	Reference Product: Humira™ Idacio™ is the eighth adalimumab biosimilar approved by the FDA. Upon launch (expected in July 2023), Idacio™ will be offered in a citrate-free, low concentration formulation in a prefilled syringe or prefilled autoinjector pen. Orphan status: No Controlled substance: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Vivimusta™ (bendamustine hydrochloride) injection for intravenous use / Slayback Pharma LLC	12/7/2022	Antineoplastics	Treatment of patients with: [1] chronic lymphocytic leukemia (CLL); [2] indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen	Vivimusta™ comes in a multiple-dose vial providing 100mg of bendamustine hydrochloride per 4mL (25mg/mL). Vivimusta™ shares the same indications as other bendamustine products already available in the market.
Iyuzeh™ (latanoprost) ophthalmic solution 0.005% / Thea Pharma Inc.	12/13/2022	Ophthalmic agents	For the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Iyuzeh™ is the first and only clinically proven form of latanoprost that is preservative-free.
Olpruva™ (sodium phenylbutyrate) for oral suspension / Acer Therapeutics Inc.	12/22/2022	Endocrine and metabolic agents – metabolic modifiers	As adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20kg or greater and with a body surface area of 1.2m^2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)	Olpruva™ is an innovative formulation of sodium phenylbutyrate packaged for the first time in single-dose envelopes.

New First-Time Generic Approvals

Generic Name, Dosage Form, Strength and Manufacturer	Generic For:	Therapeutic Class	Indications	Approval Date	Projected Launch Date
Bendamustine hydrochloride lyophilized powder for injection 25mg/vial and 100mg/vial	Treanda™	Antineoplastics	[1] Chronic lymphocytic leukemia; [2] Non-Hodgkin lymphoma	12/7/2022	First quarter 2023
Tasimelteon capsules 20mg	Hetlioz™	Hypnotics	[1] Non-24-hour sleep-wake disorder; [2] Nighttime sleep disturbances in Smith-Magenis Syndrome	12/12/2022	2023
Selexipag tablets 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg	Uptravi™	Cardiovascular agents	Pulmonary arterial hypertension	12/21/2022	10/31/2026

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Tecentriq™ (atezolizumab) injection / Genentech Inc.	Antineoplastics	[1] Non-small cell lung cancer (NSCLC); [2] small cell lung cancer; [3] hepatocellular carcinoma; [4] melanoma	Treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS)	12/9/2022
Pemfexy™ (pemetrexed) injection / Eagle Pharms	Antineoplastics	[1] Non-squamous, non-small cell lung cancer; [2] malignant pleural mesothelioma	In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations	12/14/2022
Vraylar™ (cariprazine) capsules / AbbVie	Antidepressants	[1] Schizophrenia; [2] bipolar I disorder; [3] bipolar depression	Adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults	12/16/2022

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Tymlos™ (abaloparatide) injection / Radius Health Inc.	Endocrine and metabolic agents	Osteoporosis in postmenopausal women	Treatment to increase bone density in mean with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy	12/19/2022
Actemra™ (tocilizumab) injection / Genentech Inc.	Analgesics – anti-inflammatory	[1] Rheumatoid arthritis; [2] giant cell arteritis; [3] systemic sclerosis-associated interstitial lung disease; [4] polyarticular juvenile idiopathic arthritis; [5] systemic juvenile idiopathic arthritis; [6] cytokine release syndrome	Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation	12/21/2022
Wegovy™ (semaglutide) injection / Novo Nordisk	Anti-obesity	Chronic weight management in adults	As an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity)	12/23/2022

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Nyxol™ (phentolamine) ophthalmic solution 0.75% / Ocuphire Pharma, Inc.	12/6/2022	Treatment for reversal of pharmacologically-induced mydriasis	Nyxol™ is a preservative-free, stable, investigational eye drop designed to uniquely modulate the pupil size by blocking the alpha 1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. It was granted a small business waiver of the Prescription Drug User Fee Act (PDUFA) by the FDA in September 2022. NDA submitted.	Moderate
Zuranolone / Biogen Inc. and Sage Therapeutics	12/6/2022	Treatment for major depressive disorder (MDD) and postpartum depression (PDD)	Zuranolone is an investigational drug being evaluated as a rapid-acting, once-daily, 14-day oral short course treatment in adults with MDD and PDD. It was granted Fast Track Designation by the FDA in 2017 in MDD and Breakthrough Therapy Designation in 2018. NDA submitted.	Moderate

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
PDP-716 (brimonidine tartrate 0.35%) / Visiox Pharma, LLC.	12/8/2022	Treatment of glaucoma	PDP-716 is the first once-daily brimonidine for the treatment of glaucoma. The FDA has assigned a PDUFA target action date of August 4th, 2023. NDA accepted.	Moderate
Brixadi™ (buprenorphine) extended-release injection / Braeburn	12/8/2022	Treatment of moderate to severe opioid use disorder	Brixadi™ is an investigational, extended-release subcutaneous (SC) injectable therapy (controlled substance schedule III) indicated in patients who have initiated treatment with a single dose of transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi™ will be available through a Risk Evaluation and Mitigation Strategy (REMS) program and administered only by healthcare providers in a healthcare setting. The PDUFA action date is set for May 23, 2023. NDA resubmitted.	Moderate

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Talquetamab / Janssen	12/9/2022	Treatment of patients with relapsed or refractory multiple myeloma	Talquetamab is an investigational, ready to use, bispecific T-cell engager antibody targeting both GPRC5D, a novel multiple myeloma target, and CD3 a primary component of the T-cell receptor. It has received Breakthrough Therapy and Orphan Drug designations. BLA submitted.	High high
Avasopasem manganese / Galera Therapeutics, Inc.	12/12/2022	Treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer undergoing standard-of-care treatment	Avasopasem is a selective small molecule dismutase mimetic that is designed to protect normal cells from radiation but not cancer cells. It does this by converting radiation-induced superoxide, which initiates the tissue damage and inflammatory cascade that results in oral mucositis, into hydrogen peroxide. The FDA has granted Fast Track and Breakthrough Therapy designations. NDA submitted.	High

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
MydCombi™ (tropicamide 1% and phenylephrine 2.5%) ophthalmic spray / Eyenovia, Inc.	12/13/2022	For pharmacologic mydriasis (eye dilation)	MydCombi™ is a first-in-class, drug-device combination of tropicamide and phenylephrine for in-office pupil dilation, administered via the investigational Optejet® drug delivery technology. The FDA has assigned the resubmitted NDA a standard review with a PDUFA target action date of May 8, 2023. NDA accepted.	High
Olorofim tablets / F2G Inc.	12/19/2022	Treatment of invasive fungal infections in patients who have limited or no treatment options	Olorofim is the first of the new orotomide class of antifungals that works through a novel mechanism of action, different from existing classes of antifungals, exerting fungal cell death through inhibition of the enzyme dihydroorotate dehydrogenase (DHODH) in the pyrimidine synthesis pathway. It has been granted Breakthrough Therapy and Orphan Drug designations. The PDUFA has been set for June 17, 2023.	High high

References

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