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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **FEBRUARY 2022**

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 03/08/2022

TABLE OF CONTENTS

NEWS

DRUG ISSUE	DATE	DETAILS
FDA warns about increased risk of death and serous adverse events reported in an on-going study evaluating combination treatment of Ukoniq™ with a monoclonal antibody for the treatment of chronic lymphocytic leukemia (CLL)	02/03/2022	The U.S. Food and Drug Administration (FDA) warned about an increased risk of death and serious adverse events in on-going study evaluating combination treatment of Ukoniq™ with a monoclonal antibody. Clinical trials of other drugs in the same PI3 kinase inhibitor class have shown similar safety concerns. The FDA is re-evaluating the risk versus the benefit of this medication and will continue to evaluate results from the study and stop enrollment into any studies evaluating Ukoniq™. The FDA will also consider holding a public meeting in the future to discuss the findings and continued marketing of Ukoniq™. The FDA is not recommending discontinuation of this medication; however, the agency is recommending to continue evaluating progress on the medication and to report any adverse events to the voluntary FDA reporting system.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ENJAYMO™ (SUTIMLIMAB-JOME) INJECTION	BIOVERATIV THERAPEUTICS INC.	02/04/2022

THERAPEUTIC CLASS
Hematological agents

FDA-APPROVED INDICATION(S)
Enjaymo™ is a classical component inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

DOSAGE AND ADMINISTRATION
Weight-based dosage weekly for two weeks then every two weeks:
- 6,500 mg by intravenous infusion in patients weighing 39 kg to 74 kg OR
- 7,500 mg by intravenous infusion in patients weighing more than 75 kg.

DOSAGE FORMS AND STRENGTHS
Injection: 1,100 mg/22 ml (50 mg/ml) in a single-dose vial

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with known hypersensitivity to sutimlimab-jome or any of the inactive ingredients

WARNINGS AND PRECAUTIONS
- Serious Infections: Increases susceptibility to serious infections, including infections caused by encapsulated bacteria such as *Neisseria meningitides* (any serogroup), *Streptococcus pneumoniae*, and *Haemophilus influenzae* may occur with Enjaymo™. Vaccinate patients for encapsulated bacteria at least two weeks prior to treatment. If urgent Enjaymo™ therapy is indicated in an unvaccinated patient, administer vaccine(s) as soon as possible.
- Infusion–related Reactions: Monitor for infusion-related reactions and interrupt if a reaction occurs. Discontinue infusion and institute supportive measures.
- Risk of Autoimmune Disease: Enjaymo™ may potentially increase the risk for developing autoimmune diseases such as systemic lupus erythematosus (SLE).
- Re-current Hemolysis after Enjaymo™ Discontinuation: Monitor patients for signs and symptoms of recurrent hemolysis. Consider re-starting Enjaymo™ if signs and symptoms of hemolysis occur after discontinuation.

ADVERSE REACTIONS
- The most common adverse reactions (incidence ≥10%) are respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There are no available data on Enjaymo™ use in pregnant women to evaluate for a drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
- Lactation: There are no data on the presence of sutimlimab-jome in human milk, effects on the breastfed child, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Enjaymo™ and any potential adverse effects on the breastfed child from Enjaymo™ or from the underlying maternal condition.
- Pediatric Use: The safety and effectiveness of Enjaymo™ have not been established in pediatric patients.
- Geriatric Use: No overall differences in safety or effectiveness of Enjaymo™ were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PYRUKYND™ (MITAPIVAT) TABLETS	AGIOS PHARMACEUTICALS INC.	02/17/2022

THERAPEUTIC CLASS
Hematological agents

FDA-APPROVED INDICATION(S)
Pyrukynd™ is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

DOSAGE AND ADMINISTRATION
The recommended starting dosage is 5 mg orally twice daily with or without food. Maximum recommended dose is 50mg twice daily. Dose is titrated based on hemoglobin levels and requirement of transfusion.

DOSAGE FORMS AND STRENGTHS
Tablets: 5 mg, 20 mg, and 50 mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Acute Hemolysis: Avoid abrupt interruption or abrupt discontinuation of Pyrukynd™ to minimize the risk of acute hemolysis. A gradual reduction in dosing rather than abrupt cessation is recommended when possible.

ADVERSE REACTIONS
- The most common adverse reactions including laboratory abnormalities (≥ 10%) in patients with PK deficiency were estrone decreased (males), increased urate, back pain, estradiol decreased (males), and arthralgia.

DRUG INTERACTIONS
- Strong CYP3A Inhibitors and Inducers: Avoid concomitant use.
- Moderate CYP3A Inhibitors: Do not titrate Pyrukynd™ beyond 20 mg twice daily.
- Moderate CYP3A Inducers: Consider alternatives that are not moderate inducers. If there are no alternatives, adjust Pyrukynd™ dosage.
- Sensitive CYP3A, CYP2B6, CYP2C Substrates Including Hormonal Contraceptives: Avoid concomitant use with substrates that have narrow therapeutic index.
- UGT1A1 Substrates: Avoid concomitant use with substrates that have narrow therapeutic index.
- P-gp Substrates: Avoid concomitant use with substrates that have narrow therapeutic index.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Available data from clinical trials of Pyrukynd™ are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PYRUKYND™ (MITAPIVAT) TABLETS	AGIOS PHARMACEUTICALS INC.	02/17/2022

THERAPEUTIC CLASS
Hematological Agents

FDA-APPROVED INDICATION(S)
Pyrukynd™ is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

DOSAGE AND ADMINISTRATION
The recommended starting dosage is 5 mg orally twice daily with or without food. Maximum recommended dose is 50mg twice daily. Dose is titrated based on hemoglobin levels and requirement of transfusion.

DOSAGE FORMS AND STRENGTHS
Tablets: 5 mg, 20 mg, and 50 mg

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Lactation: There are no data on the presence of Pyrukynd™ or its metabolites in human or animal milk, the effects on the breastfed child, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Pyrukynd™ and any potential adverse effects on the breastfed child from Pyrukynd™ or from the underlying maternal condition.
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric Use: Clinical studies of Pyrukynd™ did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VONJO™ (PACRITINIB) CAPSULES	CTI BIOPHARMA CORP	02/28/2022

THERAPEUTIC CLASS
Hematological agents

FDA-APPROVED INDICATION(S)
Vonjo™ is a kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

DOSAGE AND ADMINISTRATION
The recommended dosage is 200mg orally twice daily.

DOSAGE FORMS AND STRENGTHS
Capsules: 100mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Concomitant use of strong CYP3A4 inhibitors or inducers

WARNINGS AND PRECAUTIONS
- Hemorrhage: Avoid use in patients with active bleeding and hold Vonjo™ prior to any planned surgical procedures. May require dose interruption, dose reduction or permanent discontinuation depending on severity.
- Diarrhea: Manage significant diarrhea with anti-diarrheals, dose reduction, or dose interruption
- Thrombocytopenia: Manage by dose reduction or interruption.
- Prolonged QT Interval: Avoid use in patients with baseline QTc >480msec. Interrupt and reduce Vonjo™ dosage in patients who have a QTcF >500 msec. Correct hypokalemia prior to and during Vonjo™ administration
- Major Adverse Cardiac Events (MACE): Risk may be increased in current/past smokers and patients with other cardiovascular risk factors. Monitor for signs, evaluate and treat promptly.
- Thrombosis: Including deep venous thrombosis, pulmonary embolism, and arterial thrombosis may occur. Monitor for signs, evaluate and treat promptly.

WARNINGS AND PRECAUTIONS (cont.)
- Secondary Malignancies: Lymphoma and other malignancies may occur. Past/current smokers may be at increased risk.
- Risk of Infection: Delay starting Vonjo™ until active serious infections have resolved. Observe for signs and symptoms of infection and manage promptly.

ADVERSE REACTIONS
- The most common (≥20% of patients) adverse reactions are diarrhea, thrombocytopenia, nausea, anemia, and peripheral edema.

DRUG INTERACTIONS
- Strong CYP3A4 Inhibitors: Co-administration of Vonjo™ with strong CYP3A4 inhibitors is contraindicated.
- Moderate CYP3A4 Inhibitors: Avoid concomitant use.
- Strong CYP3A4 Inducers: Co-administration of Vonjo™ with strong CYP3A4 inducers is contraindicated.
- Moderate CYP3A4 Inducers: Avoid concomitant use.
- CYP1A2 or CYP3A4 Substrates: Avoid co-administration of Vonjo™ with drugs that are sensitive substrates of CYP1A2 or CYP3A4.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
VONJO™ (PACRITINIB) CAPSULES	CTI BIOPHARMA CORP	02/28/2022

THERAPEUTIC CLASS
Hematological agents

FDA-APPROVED INDICATION(S)
Vonjo™ is a kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

DOSAGE AND ADMINISTRATION
The recommended dosage is 200mg orally twice daily.

DOSAGE FORMS AND STRENGTHS
Capsules: 100mg

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS (cont.)

- P-gp, BCRP, or OCT1 Substrates: Avoid co-administration of Vonjo™ with drugs that are sensitive substrates of P-gp, BCRP, or OCT1.

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are no available data on Vonjo™ use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
- Lactation: There are no data on the presence of pacritinib in either human or animal milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with Vonjo™, and for 2 weeks after the last dose.
- Females and Males with Reproductive Potential: Pacritinib reduced male mating and fertility indices in BALB/c mice. Pacritinib may impair male fertility in humans.
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric Use: Clinical studies of Vonjo™ did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

USE IN SPECIFIC POPULATIONS (cont.)

- Hepatic Impairment: Avoid use of Vonjo™ in patients with moderate (Child-Pugh B) or severe hepatic impairment (Child-Pugh C).
- Renal Impairment: Avoid use of Vonjo™ in patients with eGFR.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
CARVYKTI™ (CILTACABTAGENE AUTOLEUCEL) SUSPENSION FOR INTRAVENOUS INFUSION	JANSSEN BIOTECH, INC.	02/28/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Carvykti™ is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agents, and an anti-CD38 monoclonal antibody.

DOSAGE AND ADMINISTRATION
Recommended dose range is 0.5-1.0×10^6 CAR-positive viable T cells per kg of body weight, with a maximum dose of 1×108 CAR-positive viable T cells per single-dose infusion. Dosing of Carvykti™ is based on the number of chimeric antigen receptor (CAR)-positive viable T cells.

DOSAGE FORMS AND STRENGTHS
Carvykti™ is a cell suspension for intravenous infusion. A single dose of Carvykti™ contains a cell suspension of 0.5-1.0×10^6 CAR-positive viable T cells per kg body weight in one infusion bag.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Boxed Warning: Cytokine release syndrome, neurologic toxicities, HLH/MAS and prolonged and recurrent cytopenia
- CARVYKTI™ REMS: Because of the risk of CRS and neurologic toxicities, Carvykti™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).
- Prolonged and Recurrent Cytopenias: Patients may exhibit ≥Grade 3 cytopenias following Carvykti™ infusion. One or more recurrences of Grade 3 or higher cytopenias may occur after partial or complete recovery of cytopenias. Monitor blood counts prior to and after Carvykti™ infusion. Prolonged neutropenia has been associated with increased risk of infection.
- Infections: Monitor patients for signs and symptoms of infection; treat appropriately.
- Hypogammaglobulinemia: Monitor and consider immunoglobulin replacement therapy.
- Hypersensitivity Reactions: Hypersensitivity reactions have occurred. Monitor for hypersensitivity reactions during infusion.

WARNINGS AND PRECAUTIONS (cont.)
- Secondary Malignancies: In the event that a secondary malignancy occurs after treatment with Carvykti™, contact Janssen Biotech, Inc. at 1-800-526-7736.
- Effects on Ability to Drive and Use Machines: Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, for at least 8 weeks after receiving Carvykti™ and in the event of any new onset of neurologic toxicities.

ADVERSE REACTIONS
- The most common nonlaboratory adverse reactions (incidence greater than 20%) are pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. The most common laboratory adverse reactions (incidence greater than or equal to 50%) include thrombocytopenia, neutropenia, anemia, aminotransferase elevation and hypoalbuminemia.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
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Recommended dose range is 0.5-1.0×10^6 CAR-positive viable T cells per kg of body weight, with a maximum dose of 1×108 CAR-positive viable T cells per single-dose infusion. Dosing of Carvykti™ is based on the number of chimeric antigen receptor (CAR)-positive viable T cells.

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Carvykti™ is a cell suspension for intravenous infusion. A single dose of Carvykti™ contains a cell suspension of 0.5-1.0×10^6 CAR-positive viable T cells per kg body weight in one infusion bag.

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS
- HIV and the lentivirus used to make Carvykti™ have limited, short spans of identical genetic material (RNA). Therefore, some commercial HIV nucleic acid tests (NATs) may yield false-positive results in patients who have received Carvykti™.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on the mechanism of action, if the transduced cells cross the placenta, they may cause fetal toxicity, including B-cell lymphocytopenia and hypogammaglobulinemia. Therefore, Carvykti™ is not recommended for women who are pregnant, or for women of childbearing potential not using contraception.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Carvykti™ and any potential adverse effects on the breastfed infant from Carvykti™ or from the underlying maternal condition.
- Females and Males of Reproductive Potential: Pregnancy status for females of child-bearing age should be verified prior to starting treatment with Carvykti™. There are insufficient data to provide a recommendation concerning duration of contraception following treatment with Carvykti™. There are no data on the effect of Carvykti™ on fertility.

USE IN SPECIFIC POPULATIONS (cont.)
- Pediatric Use: Safety and effectiveness of Carvykti™ in pediatric patients have not been established.
- Geriatric Use: CARTITUDE-1 did not include sufficient numbers of patients aged 65 and older to determine whether the effectiveness differs compared with that of younger patients. Of the 35 patients ≥65 years of age, all grade and Grade 3 and higher neurologic toxicities occurred in 37% (13/35) and 20% (7/35) respectively.

NEW BIOSMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
RELEUKO™ (FILGRASTIM-AYOW) INJECTION / KASHIV BIOSCIENCES LLC.	Hematopoietic agents	[1] Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; [2] Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML); [3] Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation BMT); [3] Reduce the incidence and duration of sequelae of severe neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia	2/25/2022	Releuko™ is the third biosimilar to Neupogen™ to be approved by the FDA after Zarxio™ and Nivestym™. Reference product: Neupogen™ Orphan: N/A

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
FLEQSUVY™ (BACLOFEN) / AZURITY PHARMACEUTICALS INC.	Musculoskeletal therapy agents	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity.	2/4/2022	Fleqsuvy™ is an oral suspension offering a more convenient approach for patients who have difficulty swallowing. In addition, patients will have the ability to titrate as tolerated and be administered a lower volume as the formulation is highly concentrated. Orphan: N/A
NEPHROSCAN™ (TECHNETIUM TC99M SUCCIMER) / THERAGNOSTICS INC.	Diagnostic products	For use as an aid in the scintigraphic evaluation of renal parenchymal disorders in adults and pediatric patients including term neonates.	2/18/2022	Nephroscan™ is a single-dose kit for the preparation of technetium Tc99m succimer injection. It binds to the cortical region of kidneys and in conjunction with gamma scintigraphy or single photon emission computed tomography is used to image the renal cortices. Orphan: Yes
NORLIQVA™ (AMLODIPINE) / CMP DEVELOPMENT, LLC.	Calcium Channel Blocker	[1] Treatment of hypertension in adults and children 6 years of age and older; [2] Treatment of coronary artery disease (CAD) including chronic stable angina, vasoplastic angina (Prinzmetal's or Variant Angina), and angiographically documented CAD in patients without heart failure or an ejection fraction <40%	2/24/2022	Norliqva™ is a calcium channel blocker offered in an oral solution for patients who may benefit from the use of an oral solution due to limitations in tolerating oral tablets. Orphan: N/A

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
ACUVUE THERAVISION™ WITH KETOTIFEN (ETAFILCON A DRUG-ELUTING CONTACT LENS WITH KETOTIFEN) FOR OPHTHALMIC USE / JOHNSON AND JOHNSON VISION CARE, INC.	Ophthalmic agents	For the prevention of ocular itch due to allergic conjunctivitis and correction of refractive ametropia (myopia and hyperopia) in aphakic and/or phakic patients who do not have red eye(s), are suitable for contact lens wear and do not have more than 1 D of astigmatism	02/25/2022	Acuvue Theravision™ is the first and only medication-releasing contact lens for patients who need vision correction and itchy eye relief. It has built-in allergy medication that starts to relieve itchy eyes in minutes, providing fast-acting and long-lasting relief, for up to 12 hours. Orphan: N/A
NALOXONE HYDROCHLORIDE INJECTION / KALEO INC.	Antidotes and specific antagonists	For use by military personnel and chemical incident responders for: [1] Emergency treatment of patients 12 years of age and older where use of high-potency opioids such as fentanyl analogues as a chemical weapon is suspected; [2] Temporary prophylaxis of respiratory and/or central nervous system depression in military personnel and chemical incident responders entering an area contaminated with high-potency opioids such as fentanyl analogues.	02/28/2022	This formulation is supplied as a 10mg/0.4mL single-dose, prefilled auto-injector. It was granted approval by the FDA through the 505(b)(2) approval pathway. Orphan: N/A

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
ASPRUZYO SPRINKLE™ (RANOLAZINE) EXTENDED-RELEASE GRANULES FOR ORAL USE / SUN PHARMA GLOBAL	Antianginal agents	For the treatment of chronic angina	02/28/2022	This new formulation of ranolazine offers a more convenient approach for patients who have difficulty swallowing. Orphan: N/A

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
CYCLOSPRORINE OPHTHALMIC EMULSION 0.05% / MYLAN PHARMACEUTICALS, INC.	Ophthalmic agents	Dry Eye Disease	Restasis™	2/2/2022
MARAVIROC TABLETS 150 MG AND 300 MG/ HETERO LABS LIMITED	Antivirals	HIV Infection	Selzentry™	2/7/2022
NALMEFENE HYDROCHLORIDE INJECTION 2 MG BASE/2 ML / PURDUE PHARMA LP	Antidotes and specific antagonists	Opioid Overdose	Revex™	2/8/2022
DAPAGLIFLOZIN TABLETS 5 MG AND 10 MG / ZYDUS PHARMACEUTICALS, INC.	Antidiabetics	Type II Diabetes	Farxiga™	2/22/2022
APOMORPHINE HYDROCHLORIDE INJECTION 30 MG/ 3 ML (10 MG/ML) / SAGE CHEMICALS, INC.	Antiparkinson and related therapy agents	Parkinson's Disease	Apokyn™	2/23/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
JUVEDERM VOLBELLA™ XC (HYALURONIC GEL) INJECTION / ALLERGAN	Dermatological	For injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds in adults over 21	For improvement of infraorbital hollows in adults over the age of 21	2/8/2022
JARDIANCE ™ (EMPAGLIFLOZIN) / BOEHRINGER INGLHEIM	Sodium-glucose co-transporter 2 Inhibitor	[1] As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; [2] To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease; [3] To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure	2/24/2022

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
OMECAMTIV MECARBIL / CYTOKINETICS, INC.	2/4//2022	Treatment of heart failure with reduced ejection fraction	Omecamtiv mecarbil is an investigational, selective, small molecule cardiac myosin activator, for the treatment of heart failure with reduced ejection fraction. Omecamtiv mecarbil will be the first of a novel class of myotropes. The NDA is supported by the results from GALACTIC-HF that demonstrated a statistically significant effect of treatment with omecamtiv mecarbil to reduce risk of the primary composite endpoint of cardiovascular (CV) death or heart failure events (heart failure hospitalization and other urgent treatment for heart failure) compared to placebo in patients treated with standard of care. NDA accepted.	High
POZIOTINIB / SPECTRUM PHARMACEUTICALS, INC.	2/11/2022	For use in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations	Poziotinib is a tyrosine kinase inhibitor in development for the treatment of non-small cell lung cancer. The NDA acceptance is based on the positive Phase 2 study results in patients with previously treated locally advanced or metastatic NSCLC harboring HER2 exon 20 insertion mutations. Poziotinib will be the first with approval from the FDA for this specific indication. The product has received fast track designation. NDA accepted.	High
ADAGRASIB / MIRATI THERAPEUTICS, INC.	2/15/2022	For the treatment of patients with NSCLC harboring the $KRAS^{G12C}$ mutation who have received at least one prior systemic therapy	The FDA is reviewing adagrasib via accelerated approval and this drug has achieved Breakthrough Therapy Designation. The NDA is based on the Phase 2 cohort of the KRYSTAL-1 study, evaluating adagrasib in patients with advanced NSCLC harboring the $KRAS^{G12C}$ mutation following prior treatment with immunotherapy and chemotherapy. The Company reported positive topline data from this cohort in September 2021, and plans to present detailed results at a medical conference during the first half of 2022. NDA accepted.	High

REFERENCES

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