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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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NEWS

Drug issue	Date	Details
Avoid Use of NSAIDs in Pregnancy at 20 Weeks or Later	10/15/2020	The FDA issued a warning to avoid the use of Non-steroidal Anti-inflammatory Drugs (NSAIDs) during pregnancy at 20 weeks or later. The use of NSAIDs around 20 weeks or later in pregnancy may cause serious kidney problems in the fetus, low levels of amniotic fluids, and other complications. Previously NSAIDs labels warned to avoid use during the last three (3) months of pregnancy due to the risk of premature closure of the fetal ductus arteriosus. The FDA now requires changes in the prescribing information for both prescription and over the counter (OTC) NSAIDs. Recommendations for healthcare professionals: • Advise pregnant women to avoid the use of NSAIDs at 20 weeks of pregnancy or later. • If NSAIDs are necessary during 20 to 30 weeks of pregnancy, limit treatment to the lowest dose possible and for the shortest duration. Consider ultrasound monitoring of amniotic fluid if treatment extends over 48 hours. If low levels of amniotic fluid are identified, discontinue the NSAID. • These recommendations do not apply to low dose 81mg aspirin prescribed for certain conditions in pregnancy. • Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn) Injection, for intravenous use	Regeneron Pharmaceuticals, Inc.	10/14/2020

THERAPEUTIC CLASS
Anti-infective agent

FDA-APPROVE INDICATION(S)
Inmazeb™ is a combination of *Zaire ebolavirus* glycoprotein-directed human monoclonal antibodies indicated for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Zaire ebolavirus* infection .

DOSAGE AND ADMINISTRATION
The recommended dose is 50 mg of atoltivimab, 50 mg of maftivimab, and 50 mg of odesivimab per kg diluted and administered as a single intravenous infusion.

DOSAGE FORMS AND STRENGTHS
Injection: 241.7 mg of atoltivimab, 241.7 mg of maftivimab, and 241.7 mg of odesivimab per 14.5 mL (16.67 mg/16.67 mg/16.67 mg per mL) in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions Including Infusion-Associated Events

ADVERSE REACTIONS
Most common adverse reactions: pyrexia, chills, tachycardia, tachypnea, and vomiting.

DRUG INTERACTIONS
- live vaccine indicated for prevention of Zaire ebolavirus Infection: No vaccine interaction studies have been performed. However, Inmazeb™ may reduce the efficacy of the live vaccine. The interval between live vaccination following initiation of Inmazeb™ therapy should be in accordance with current vaccination guidelines.

USE IN SPECIFIC POPULATIONS
- Pregnancy: *Zaire ebolavirus* infection is life-threatening for both the mother and fetus and treatment should not be withheld due to pregnancy.
- Lactation: Patients infected with *Zaire ebolavirus* should be instructed not to breastfeed due to the potential for Zaire ebolavirus transmission.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Veklury™ (remdesivir) Injection, for intravenous use	Gilead Sciences, Inc.	10/22/2020

THERAPEUTIC CLASS
Anti-infective agent

FDA-APPROVE INDICATION(S)
Veklury™ is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for adults and pediatric patients (≥12 years and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

DOSAGE AND ADMINISTRATION
The recommended dose is a single loading dose of 200mg on Day 1 followed by once-daily maintenance doses of 100mg from Day 2 by intravenous infusion. The recommended total treatment duration:

- For patients not requiring invasive mechanical ventilation and/or ECMO: 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
- For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.

DOSAGE FORMS AND STRENGTHS

- For injection: 100 mg of remdesivir as a lyophilized powder, in single-dose vial.
- Injection: 100 mg/20 mL (5 mg/mL) remdesivir, in single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS

- History of clinically significant hypersensitivity reactions to Veklury™ or any components of the product.

WARNINGS AND PRECAUTIONS

- Hypersensitivity including infusion-related and anaphylactic reactions
- Increased risk of transaminase elevations
- Risk of reduced antiviral activity when co-administered with chloroquine phosphate or hydroxychloroquine sulfate

ADVERSE REACTIONS
Most common adverse reactions: nausea, ALT increased, and AST increased.

DRUG INTERACTIONS

- Chloroquine phosphate or hydroxychloroquine sulfate: Due to antagonism observed in cell culture, concomitant use is not recommended.

USE IN SPECIFIC POPULATIONS

- Pediatric use: Safety and effectiveness have not been established in pediatric patients younger than 12 years of age or weighing less than 40 kg.
- Geriatric use: Reported clinical experience has not identified differences in responses between the elderly and younger patients. Appropriate caution should be exercised in elderly patients, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- Renal impairment: All patients must have an eGFR determined before starting and during treatment as clinically appropriate. Because the excipient betadex sulfobutyl ether sodium is renally cleared and accumulates in patients with decreased renal function, administration of drugs formulated with betadex sulfobutyl ether sodium is not recommended in patients with eGFR less than 30 mL per minute.
- Hepatic impairment: Perform hepatic laboratory testing in all patients before starting and during treatment as clinically appropriate.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Eysuvis™ (loteprednol etabonate) Ophthalmic Suspension / Kala Pharmaceuticals, Inc.	Ophthalmic agent; Corticosteroid	Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease	10/26/2020	Eysuvis™ is a new ophthalmic suspension of loteprednol etabonate 0.25%, which comes to be the first prescription therapy specifically developed to address the short-term treatment needs of people living with dry eye disease. Although other ophthalmic drug products containing loteprednol etabonate (branded and generic) were already available in the market, they have other uses such as steroid-responsive conjunctivitis, post-operative inflammatory disorder of the eye, and seasonal allergic conjunctivitis. Orphan status: N/A
Bronchitol™ (mannitol) Inhalation Powder, for oral inhalation use / Chiesi USA, Inc.	Respiratory agent;	Add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis	10/30/2020	Bronchitol™ is an oral inhalation powder of mannitol to be used only in adults who have passed the BRONCHITOL Tolerance Test. Although other mannitol-containing drug products were already available in the market, they are injection/intravenous solutions (branded and generic) for other uses such as inhalation bronchial challenge testing, irrigation of urinary bladder, raised intracranial pressure, and raised intraocular pressure. Orphan status: Orphan

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma	In combination with Yervoy™ (ipilimumab), for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM)	10/02/2020
Wakix™ (pitolisant) Tablets / Harmony Biosciences, LLC	Central nervous system agent	Treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy	Treatment of cataplexy in adult patients with narcolepsy	10/13/2020
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma	As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma	10/14/2020
Venclexta™ (venetoclax) Tablets / AbbVie Inc.	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	Treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	In combination with azacitidine, or decitabine, or low-dose cytarabine (LDAC) for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy • Full approval granted; Venclexta was previously granted provisional approval in this setting under the FDA's accelerated approval program in November 2018	10/16/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Indication(s)	Generic for:	Date:
Fosfomycin Tromethamine Granules for Oral Solution 3 grams (base)/single-dose sachet / Xiromed Pharma España, S.L	Anti-infective agent	Uncomplicated urinary tract infection in women	Monurol	10/06/2020
Azelaic Acid Topical Foam 15% / Teva Pharmaceuticals USA, Inc.	Dermatological agent	Rosacea	Finacea	10/07/2020
Tavaborole Topical Solution 5% / Perrigo Pharma International DAC; Encube Ethicals Private Limited	Antifungal	Onychomycosis of the toenails	Kerydin	10/13/2020
Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg / Breckenridge Pharmaceutical, Inc.; Eugia Pharma Specialities Ltd.	Antineoplastic agent	• Kaposi's sarcoma, HIV-negative or AIDS-related disease after failure of HAART • Multiple myeloma	Pomalyst	10/30/2020

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Pacritinib / CTI BioPharma Corp.	10/13/2020	Treatment for: Myelofibrosis	Pacritinib is an investigational oral JAK2/FLT3 multikinase inhibitor in development for the treatment of myelofibrosis patients with severe thrombocytopenia. CTI BioPharma Corp. has commenced a rolling NDA submission.	High

References

- Food and Drug Administration (www.fda.gov)
- Drugs.com (www.drugs.com)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
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