CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
McWhorter School of Pharmacy

NEW DRUG FAX SHEET

http://www.samford.edu/go/chipor

Volume 24 (Issue 4) **April 15, 2019**

This issue of *New Drug FAX Sheet* briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications. If you need further information, please contact the Center for Healthcare Innovation and Patient Outcomes Research (CHIPOR) at chipor@samford.edu.

NEW DRUG APPROVALS

Esketamine (Spravato, Janssen Pharms)
Pharmacology: Non-competitive N-methyl D-aspartate (NMDA) receptor antagonist.
Indication: Treatment-resistant depression in adults, in combination with an oral antidepressant.
Adverse Drug Reactions: Dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.
Dose: Varies based on induction and maintenance phase. Starting dose on day 1 is 56 mg, administered twice weekly. A dose of 56 or 84 mg may be administered once weekly during weeks 5-8. Week 9 and after, 56 mg or 84 mg can be administered every 2 weeks or once weekly.
Formulation: Nasal spray containing esketamine 28 mg per device. Each device delivers two sprays containing 28 mg of esketamine.
Warnings/Contraindications: Increases in blood pressure; cognitive impairment; impaired ability to drive and operate machinery; and embryo-fetal toxicity.
Notes: Do not administer to patients with uncontrolled blood pressure.

Trastuzumab-QYYP (Trazimera, Pfizer)
Pharmacology: HER2/neu receptor antagonist.
Indication: Treatment of HER2-overexpressing breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma.
Adverse Drug Reactions: Headache, diarrhea, nausea, chills, congestive heart failure, insomnia, cough, rash, neutropenia, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.
Dose: Varies, based on indication. Initial dose of 4-8 mg/kg over 90 minutes.
Formulation: Lyophilized powder for injection (420 mg).
Warnings/Contraindications: Exacerbation of chemotherapy-induced neutropenia.
Notes: Administration may result in sub-clinical and clinical cardiac failure.

Netarsudil; Latanoprost (Rocklatan, Aerie Pharms Inc.)
Pharmacology: Fixed dose combination of a Rho kinase inhibitor and a prostaglandin F_{2alpha} analogue.
Indication: Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
Adverse Drug Reactions: Conjunctival hyperemia, instillation site pain, corneal verticillata, and conjunctival hemorrhage.
Dose: One drop in the affected eye (s) once daily in the evening.
Formulation: Ophthalmic solution containing netarsudil 0.2 mg/mL (0.02%) and latanoprost 0.05 mg/mL (0.005%).
Warnings/Contraindications: Change in pigmentation of iris, periorbital tissue and eyelashes; increased length, thickness, and number of lashes.
Notes: Separate doses of ophthalmic drug by at least 5 minutes.

Ceritinib (Zykadia, Novartis Pharms)
Pharmacology: Kinase inhibitor.
Indication: Treatment of metastatic non-small cell lung cancer in adults whose tumors are anaplastic lymphoma kinase (ALK)-positive.
Adverse Drug Reactions: Diarrhea, nausea, abdominal pain, vomiting, and fatigue.
Dose: 450 mg orally once daily with food.
Formulation: Capsules/tablets - 150 mg.

CONTINUED NEXT PAGE

Ceritinib (Zykadia, Novartis Pharms) (continued)
Warnings/Contraindications: Gastrointestinal adverse reactions, hepatotoxicity, interstitial lung disease/pneumonitis, QT interval prolongation, hyperglycemia, bradycardia, pancreatitis, and embryo-fetal toxicity.
Notes: Avoid concomitant use with ceritinib and CYP3A inhibitors, inducers, and substrates. Avoid coadministration of ceritinib with CYP2C9 substrates.

Brexanolone (Zulresso, Sage Therapeutics)
Pharmacology: Neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator.
Indication: Treatment of postpartum depression.
Adverse Drug Reactions: Sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush.
Dose: The product is administered as a continuous infusion over 60 hours (2.5 days).
Formulation: Injection 100 mg/20 mL (5 mg/mL) single-dose vial.
Warnings/Contraindications: Suicidal thoughts and behaviors.
Notes: Avoid use in patients with end stage renal disease (ESRD).

Solriamfetol (Sunosi, Jazz Pharma)
Pharmacology: Dopamine and norepinephrine reuptake inhibitor (DNRI).
Indication: Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).
Adverse Drug Reactions: Headache, nausea, decreased appetite, insomnia, and anxiety.
Dose: The starting dose for narcolepsy is 75 mg once daily and 37.5 mg for OSA. The dose may be increased at interval of at least 3 days. The maximum dose is 150 mg once daily.
Formulation: Tablets, 75 mg and 150 mg.
Warnings/Contraindications: Contraindicated with concomitant treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days; blood pressure and heart rate increases; and psychiatric symptoms.
Notes: Use with caution with drugs that increase blood pressure and/or heart rate and dopaminergic drugs.

Siponimod (Mayzent, Novartis Pharms Corp.)
Pharmacology: Spingosine 1-phosphate modulator.
Indication: Treatment of relapsing forms of multiple sclerosis.
Adverse Drug Reactions: Headache, hypertension, and transaminase increases.
Dose: The recommended maintenance dose is 2 mg; however, patients with certain CYP2C9 genotypes may require a 1 mg dose.
Formulation: Tablets 0.25 mg and 2 mg.
Warnings/Contraindications: Patients with CYP2C9*3/3* genotype; experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class II/IV heart failure within the last 6 months; and presence of Mobitz type II second-degree, third-degree AV block or sick sinus syndrome; infection risk may be increased; macular edema; bradyarrhythmia and atrioventricular conduction delays; respiratory effects; liver injury; increased blood pressure; fetal risk.
Notes: Avoid live attenuated vaccines during and for up to 4 weeks after treatment.

NEW DRUG FORMULATIONS

Tetracaine Hydrochloride (Tetracaine Hydrochloride, Bausch Health Ireland Limited)
Pharmacology: Topical ocular anesthetic.
Indication: Procedures requiring a rapid and short-acting topical ophthalmic anesthetic.
Dosage form: Ophthalmic solution.
Dose: One drop topically in the eye as needed.

Efavirenz; Lamivudine; Tenofovir Disoproxil Fumarate (Efavirenz; Lamivudine; Tenofovir Disoproxil Fumarate Macleods Pharms Ltd)
Pharmacology: A non-nucleoside reverse transcriptase inhibitor and nucleo(t)side reverse transcriptase inhibitor.
Indication: Treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 mg.
Dosage form: Tablets containing efavirenz 400 mg, lamivudine 300 mg, and tenofovir 300 mg.
Dose: One tablet daily orally on an empty stomach, preferably at bedtime.

CONTINUED NEXT PAGE

Testosterone Undecanoate (Jatenzo, Clarus Therapeutics, Inc.)
Pharmacology: Androgen.
Indication: Testosterone replacement therapy in adult males.
Dosage form: Capsules (158 mg, 198 mg, and 237 mg).
Dose: The starting dose is 237 mg orally once in the morning and evening. The dose can be adjusted to a maximum of 396 mg twice daily.

Cladribine (Mavenclad, EMD Serono, Inc.)
Pharmacology: Purine antimetabolite.
Indication: Relapsing forms of multiple sclerosis.
Dosage form: Tablets, 10 mg.
Dose: Cumulative dosage of 3.5 mg/kg administered orally and divided into 2 treatment courses.

Acyclovir (Avaclyr, Fera-Pharms, LLC))
Pharmacology: Herpes simplex virus nucleoside analog DNA polymerase inhibitor.
Indication: Treatment of actue herpetic keratitis.
Dosage form: Sterile ointment.
Dose: 1 cm ribbon in the lower cul-de-sac of the affected eye 5 times per day until healed, then 3 times per day for 7 days.

Aclidinium Bromide; Formoterol Fumarate Dihydate Duaklir Pressair, AstraZeneca Pharms)
Pharmacology: Longo-acting beta$_2$-adrenergic agonist (LABA).
Indication: Maintenance treatment of patients with chronic obstructive pulmonary disease.
Dosage form: 400 mcb of aclidinium bromide and 12 mcg of formoterol fumarate per actuation.
Dose: 400 mcg/12 mcg twice daily.

Prepared by: Maisha Kelly Freeman, PharmD, MS, BCPS, FASCP