CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY SAMFORD UNIVERSITY
Preparing Pharmacists Who Transform Lives®

NEW DRUG FAX SHEET

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

Volume 21 (Issue 5) **May 16, 2016**

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

Inflixamab-dyyb(Inflectra, Celltrion, Inc.)
Pharmacology: Tumor necrosis factor.
Indication: Crohn's disease (adults and pediatrics), ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis,
Adverse Drug Reactions: Infections (e.g., upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.
Dose: Dose is dependent upon indication; however, the dose is administered via intravenous infusion. Dose can range from 3-5 mg/kg at 0, 2, and 6 weeks.
Formulation: Single-use vials containing 100 mg of infliximab-dyyb for final reconstitution volume of 10 mL.
Warnings/Contraindications: Doses >5 mg/kg is contraindicated in moderate to severe heart failure. Serious infections, malignancies, hepatotoxicities, heart failure, hypersensitivity, demyelinated diseases may occur with therapy. Live vaccines or therapeutic infectious agents should not be given with the drug.
Notes: Use with anakinra or abatacept may increase the risk of serious infections.

Venetoclax (Venclexta, AbbVie, Inc.)
Pharmacology: BCL-2 inhibitor.
Indication: Treatment of patients with chronic lymphocytic leukemia.
Adverse Drug Reactions: Neutropenia, diarrhea, nausea, anemia, upper respiratory tract infection, thrombocytopenia, and fatigue.
Dose: Initial therapy is 20 mg once daily for 7 days, then a weekly increase in dosing schedule is recommended up to a dose of 400 mg. Tablets should be taken orally once daily with a meal and water.
Formulation: Tablets: 10 mg, 50 mg, and 100 mg.
Warnings/Contraindications: Concomitant use with strong CYP3A inhibitors at initiation and during the dosage increase is contraindicated. Tumor lysis syndrome, neutropenia, and embryo-fetal toxicity may occur. Live vaccinations should not be administered prior to, during or after treatment.
Notes: Do not chew, crush, or break tablets.

Cabozantinib (Cabometyx, Exelixis, Inc.)
Pharmacology: Kinase inhibitor.
Indication: Indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior antiangiogenic therapy.
Adverse Drug Reactions: Diarrhea, fatigue, nausea, decreased appetite, palmar-plantar erthryodysesthesia syndrome (PPES), hypertension, vomiting, weight decreased and constipation.
Dose: 60 mg orally, once daily.
Formulation: Tablets: 20, 40, and 60 mg.
Warnings/Contraindications: Hemorrhage, GI perforations and fistulas, thrombotic events, hypertension/hypertensive crisis, diarrhea, reversible posterior leukoencephalopathy syndrome (RPLS), and embryo-fetal toxicity.
Notes: The dosage of cabozantinib should be reduced with concomitant use of strong CYP3A4 inhibitors and the dosage should be increased with strong CYP3A4 inducers.

Pimavanserin (Nuplazid, Acadia Pharmaceuticals)
Pharmacology: Atypical antipsychotic.
Indication: Treatment of hallucinations and delusions associated with Parkinson's disease.
Adverse Drug Reactions: Peripheral edema and confusional state.
Dose: 34 mg taken orally as two 17 mg tablets once daily.
Formulation: 17-mg tablets.

CONTINUED NEXT PAGE

NEW DRUG APPROVALS (CONTINUED)

Pimavanserin (Nuplazid, Acadia Pharmaceuticals) (continued)
Warnings/Contraindications: QT prolongation.
Notes: Dosage of pimavanserin should be reduced by one half with concomitant CYP3A4 inhibitor use and an increase in pimavanserin dose be considered with strong CYP3A4 inducers.

NEW DRUG FORMULATIONS

Emtricitamine (FTC), tenofovir alafenamide (TAF) (Descovy, Gilead Sciences, Inc.)
Pharmacology: HIV nucleoside analog reverse transcriptase inhibitors (NRTI).
Indication: Treatment of HIV-1 infection in patients.
Dosage form: Tablets: 200 mg FTC and 25 mg TAF.
Dose: One tablet daily with or without food in patients with a body weight of at least 35 kg and a creatinine clearance $\geq$ 30 mL/min.

Glycopyrrolate and formoterol fumarate (Bevespi Aerosphere, AstraZeneca Pharmaceuticals, LP)
Pharmacology: Anticholinergic, long-acting beta$_2$ adrenergic agonist (LABA).
Indication: Long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).
Dosage form: Metered dose inhaler containing glycopyrrolate (9 mcg) and formoterol fumarate (4.8 mcg).
Dose: Two inhalations twice daily.

Perampanel oral suspension (Fycompa, Eisai, Inc.)
Pharmacology: Noncompetitive AMPA glutamate receptor antagonist.
Indication: Adjunctive therapy for partial-onset seizures and primary generalized tonic-clonic seizures with epilepsy.
Dosage form: Oral suspension 0.5 mg/mL.
Dose: The starting dose is 2 mg once daily. The dosage can be increased to up to 12 mg daily.

NEW DRUG INDICATIONS

Afatinib (Gilotrif, Boehringer Ingelheim, Inc)
Pharmacology: Kinase inhibitor.
Indication: Previously treated, metastatic squamous NSCLC.
Dose: 40 mg orally once daily.