CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
McWhorter School of Pharmacy

NEW DRUG FAX SHEET

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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

Gemtuzumab Ozogamicin (Mylotarg, Pfizer)
Pharmacology: CD33-directed antibody drug conjugate.
Indication: Newly diagnosed CD33-positive acute myeloid leukemia (AML) in adults; treatment of relapsed or refractory CD33-positive AML in adults and in children aged ≥ 2 years.
Adverse Drug Reactions: Hemorrhage, infection, fever, nausea, vomiting, constipation, headache, increased AST/ALT, rash, and mucositis.
Dose: Various regimens based on newly diagnosed disease for induction, consolidation, continuation therapy or relapsed or refractory AML.
Formulation: Single-dose vial of 4.5 mg lypholized cake or powder.
Warnings/Contraindications: Infusion-related reactions, hemorrhage, and embryo-fetal toxicity.
Notes: Premedicate with a corticosteroid, antihistamine and acetaminophen 1 hour prior to administration of gemtuzumab.

Copanlisib (Aliqopa, Bayer Healthcare Pharmaceuticals, Inc.)
Pharmacology: Kinase inhibitor.
Indication: Treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.
Adverse effects: Hyperglycemia, diarrhea, decreased strength and energy, hypertension, leukopenia, neutropenia, nausea, lower respiratory tract infections, and thrombocytopenia.
Dose: 60 mg administered as a 1-hour intravenous infusion on days 1, 8, 15, and 28-day treatment on an intermittent schedule (three weeks on and one week off).
Formulation: Single-dose vial of 60 mg lypholized solid.
Warnings/Contraindications: Infections, hyperglycemia, hypertension, neutropenia, severe cutaneous reactions, embryo-fetal toxicity, and non-infectious pneumonitis.
Notes: Avoid CYP3A inducers and inhibitors. Reduce dose to 45 mg when concomitantly administering strong CYP3A inhibitors.

Bevacizumab-AWWB (Mvasi, Amgen)
Pharmacology: Vascular endothelial growth-factor specific angiogenesis inhibitor.
Indication: Metastatic colorectal cancer in combination with 5-flurouracil; metastatic colorectal cancer; non-squamous non-small cell lung cancer; gioblastoma; metastatic renal cell carcinoma; and cervical cancer.
Adverse Drug Reactions: Epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, and exfoliative dermatitis.
Dose: Various dosages based on indication.
Formulation: Injection, available as 100 mg/4 mL or 400 mg/16 mL single-dose vial.
Warnings/Contraindications: Performation or fistula, arterial thromboembolic events, venous thromboembolic events (VTE), hypertension, posterior reversible encephalopathy syndrome, proteinuria, infusion reactions, embryo-fetal toxicity, and ovarian failure.
Notes: Do not administer or mix with dextrose solution.

Secinadozole (Solosec, Symbiomix Therapeutics, LLC.)
Pharmacology: Nitroimadazole antimicrobial.
Indication: Bacterial vaginosis in adults.
Adverse Drug Reactions: Vulvo-vaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.

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Secinadozole (Solosec, Symbiomix Therapeutics, LLC.) (continued)
Dose: 2-gram packet of granules orally, once daily.
Formulation: Oral granules, 2g.
Warnings/Contraindications: Vulvo-vaginal candidiasis, risk for cardinogenicity.
Notes: Do not dissolve in liquid. Discontinue breastfeeding for 96 hours after administration of secnidazole.

Abemaciclib (Verzenio, Eli Lilly and Co.)
Pharmacology: Kinase inhibitor.
Indication: Combination treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer; and as monotherapy for HR positive, HER2 negative advanced or metastatic breast cancer with disease progression.
Adverse Drug Reactions: Diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, and thrombocytopenia.
Dose: Combination therapy: 150 mg twice daily; monotherapy: 200 mg twice daily.
Formulation: 50-mg, 100-mg, 150-mg, and 200-mg tablets.
Warnings/Contraindications: Diarrhea, neutropenia, hepatotoxicity, VTE, embryo-fetal toxicity.
Notes: Avoid concomitant use of ketoconazole and strong CYP3A inducers.

NEW DRUG FORMULATIONS

Bosentan Tracleer, Actelion Pharmaceuticals LTD)
Pharmacology: Endothelin receptor antagonist.
Indication: Pulmonary arterial hypertension.
Dosage form: Film-coated tablets 62.5 mg, 125 mg; tablet for oral suspension 32 mg.
Dose: 62.5 mg orally twice daily for patients weighing >40 kg; increase to 125 mg orally twice daily after 4 weeks.

Amphetamine (Adzenys ER, Neos Theraps, Inc)
Pharmacology: Central nervous system (CNS) stimulant.
Indication: Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years.
Dosage form: Extended-release oral suspension containing 1.25 mg amphetamine per mL.
Dose: Patients ages 6-17 years: 6.3 mg (max 18.8 mg); Adults: 12.5 mg once daily in the morning.

Fluticasone Propionate (Xhance, Optnose US, Inc.)
Pharmacology: Corticosteroid.
Indication: Treatment of nasal polyps in adults.
Dosage form: Nasal spray: 93 mcg in each 106-mg spray.
Dose: One spray per nostril twice daily. Two sprays per nostril twice daily may be efficacious in some patients.

Fluticasone furoate; umeclidinium; vilanterol (Trelegy Ellipta, GlaxoSmithKline)
Pharmacology: Combination of inhaled corticosteroid (ICS), anticholinergic, and long-acting beta$_2$adrenergic agonist (LABA).
Indication: Long-term, once daily maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
Dose: One inhalation once daily.

Chlorprocaine Hydrochloride (Clorotekal, Sintetica SA)
Pharmacology: Local anesthetic.
Indication: Production of subarachnoid block (spinal anesthesia).
Dosage form: 5 mL type 1 clear glass ampoule comtaining 50 mg chlorprocaine.
Dose: The dose for an average adult is 50 mg.

Insulin Aspart (Fiasp, Novo Nordisk, Inc.)
Pharmacology: Rapid-acting human insulin analog.
Indication: Improve glycemic control in adults with diabetes mellitus.
Dosage form: Injection-100 units/mL; 10 mL multiple-dose vial and 3 mL single patient use FIASP FlexTouch pen.
Dose: Individualized based on patient's individual needs.