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 6) **June 20, 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 (205) 726-2659.

NEW DRUG APPROVALS

Atezolizumab (Tecentriq, Genentech Inc)
Pharmacology: Anti-programmed death-ligand 1 (PD-L1) antineoplastic agent.
Indication: Second-line therapy for locally advanced or metastatic urothelial carcinoma.
Adverse Drug Reactions: Fatigue, nausea, constipation, decreased appetite, peripheral edema, colitis.
Dose: 1200 mg infusion over 60 minutes every 3 weeks. May infuse over 30 minutes if first infusion is tolerated.
Formulation: Solution for injection: 1200 mg/ 20 mL.
Warnings/Contraindications: Adrenal insufficiency; hyper- or hypothyroidism; new-onset diabetes; pancreatitis; severe infection; infusion reactions; motor sensory neuropathy; fetal harm; immune-mediated pneumonitis, hepatitis, endocrinopathies, myasthenic syndrome/myasthenia gravis, Guillain-Barre or meningoencephalistis; or interstitial lung disease.
Notes: Females should avoid pregnancy and breastfeeding at least 5 months after the last dose. Monitor liver and thyroid function tests.

Antihemophilic Factor (recombinant), single chain (Afstyla, CSL Behring)
Pharmacology: Antihemophilic agent.
Indication: Hemophilia.
Adverse Drug Reactions: Dizziness, hypersensitivity reactions.
Dose: Typical prophylactic dose ranges from 20 – 50 IU/kg 2-3 times weekly. One IU/kg body weight equates to a 2 IU/dL increase in Factor VIII. Higher or more frequent dosing may be required in pediatric patients.
Formulation: Lyophilized powder: 250 IU, 500 IU, 1000 IU, 2000 IU, or 3000 IU.
Warnings/Contraindications: Contraindicated in patients who have hypersensitivity to hamster proteins. Neutralizing antibodies may form, and hypersensitivity reactions can occur.
Notes: Not indicated for the treatment of von Willebrand disease.

Daclizumab (Zinbryta, Biogen)
Pharmacology: Interleukin 2 receptor blocking antibody.
Indication: Multiple Sclerosis.
Adverse Drug Reactions: Nasopharyngitis, upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal pain, and lymphadenopathy.
Dose: 150 mg once monthly.
Formulation: Prefilled syringe for subcutaneous injection: 150 mg/mL.
Warnings/Contraindications: Contraindicated for patients with preexisting hepatic disease or hepatic impairment (including ALT or AST ≥ 2 times the ULN) as well as those with autoimmune hepatitis or any autoimmune condition involving the liver.
Notes: This product will be available through a REMS program. Not recommended for pediatric patients, or those who are pregnant or breastfeeding.

Linagliptin and metformin (Jentadueto XR, Boehringer Ingelheim)
Pharmacology: Dipeptidyl peptidase-4 (DPP-IV) inhibitor, biguanide.
Indication: Type 2 diabetes mellitus.
Adverse Drug Reactions: Flatulence, nausea, vomiting, diarrhea, nasopharyngitis, hypoglycemia, lactic acidosis, hypersensitivity, pancreatitis
Dose: Oral: 2.5 mg linagliptin/500 mg metformin if not currently treated with metformin; 5 mg linagliptin/1000 mg if patient is currently being treated with metformin or linagliptin plus metformin.

CONTINUED NEXT PAGE

Linagliptin and metformin (Jentadueto XR, Boehringer Ingelheim) (continued)
Formulation: Extended-release oral tablet: 2.5 mg linagliptin/1000 mg metformin and 5 mg linagliptin/1000 mg metformin.
Warnings/Contraindications: Contraindicated for patients with eGFR below 30 mL/min or those with a history of acute or chronic metabolic acidosis, including diabetic ketoacidosis. Avoid for patients with hepatic disease
Notes: Take with meal to reduce gastrointestinal adverse effects. Safety and effectiveness have not been established in pediatric patients.

Obeticholic acid (Ocaliva, Intercept Pharmaceuticals Inc)
Pharmacology: Farnesoid X receptor (FXR) agonist
Indication: Add-on to ursodeoxycholic acid for primary biliary cirrhosis
Adverse Drug Reactions: Pruritus, fatigue, abdominal pain, arthralgia, asthenia, decreased HDL cholesterol, ocular pruritus, rash, and urticaria.
Dose: Oral: 5 mg once daily. May titrate to 10 mg after 3 months if inadequate response.
Formulation: Oral tablet: 5 mg and 10 mg.
Warnings/Contraindications: Contraindicated for patients with complete biliary obstruction. Monitor for worsening ascites, jaundice, primary biliary cholangitis flare, and moderate to severe hepatic impairment.
Notes: Safety and efficacy have not been established in pediatric patients. May increase exposure to drugs that are substrates of CYP1A2.

NEW DRUG FORMULATIONS

Aminolevulinic acid HCl (Ameluz, Biofrontera Pharma AG)
Pharmacology: Photosensitizing agent.
Indication: Mild-to-moderate actinic keratosis of the face and scalp.
Dosage form: Topical gel: 78 mg
Dose: Apply to actinic keratoses no more than once every 8 weeks; follow with blue light illumination 14-18 hours after application.

Buprenorphine (Probuphine, Titan Pharms)
Pharmacology: Mu-opioid receptor partial agonist; kappa-opioid antagonist.
Indication: Maintenance treatment of opioid dependence.
Dosage form: Implant.
Dose: Implant contains 74.2 mg; equivalent to 80 mg buprenorphine hydrochloride.

NEW DRUG INDICATIONS

Nivolumab (Opdivo, Bristol-Myers Squibb)
Pharmacology: Antineoplastic agent; Anti-PD-1 monoclonal antibody.
New Indication: Hodgkins lymphoma
Dose: IV: 3 mg/kg once every 2 weeks.

Lenvatinib (Lenvima, Eisai)
Pharmacology: Antineoplastic agent; tyrosine kinase inhibitor.
New Indication: Advanced renal cell carcinoma.
Dose: Oral: 18 mg once daily in combination with everolimus 5 mg daily.