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

Guselkumab (Tremfya, Janssen Biotech)
Pharmacology: Interleukin-23 blocker.
Indication: Treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Adverse Drug Reactions: Upper respiratory infections (URTI), headache, injection site reaction, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simplex infection.
Dose: 100 mg subcutaneous injection at week 0, 4, and every 8 weeks thereafter.
Formulation: 100 mg/mL in a single dose prefilled syringe.
Warnings/Contraindications: Tuberculosis (TB), increased risk of infection. Avoid use of live vaccines.
Notes: Avoid the use of live vaccines in patients treated with guselkumab.

Pitavastatin (Zypitamag, Zydus Pharms USA INC)
Pharmacology: HMG-CoA reductase inhibitor.
Indication: Treatment of hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol, low density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase high-density lipoprotein cholesterol.
Adverse Drug Reactions: Myalgia, back pain, diarrhea, constipation, and pain in extremities.
Dose: 1-mg, 2-mg, or 4-mg once daily.
Formulation: 1-mg, 2-mg, and 4-mg oral tablets.
Warnings/Contraindications: Hypersensitivity reactions, myopathy, rhabdomyolysis, liver enzyme abnormalities.
Notes: Advise women to use effective contraception during treatment. Safety and effectiveness has not been established in pediatrics. Do not administer with cyclosporine.

Neratinib (Nerlynx, Puma Biotech Inc)
Pharmacology: Kinase inhibitor.
Indication: Extended adjuvant treatment of adults with early stage HER-2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.
Adverse Drug Reactions: Diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distension, weight decrease, and urinary tract infection (UTI).
Dose: 240 mg (6 tablets) orally daily with food continuously for one year.
Formulation: Oral 40-mg tablet.
Warnings/Contraindications: Diarrhea, hepatotoxicity, and embryo-fetal toxicity.
Notes: Avoid concomitant use with proton pump inhibitors and H_2 antagonist separated by 3 hours after antacid dosing. Avoid strong or moderate CYP3A4 inhibitors or inducers.

Sofosbuvir; Velpatasvir; Voxilaprevir (Vosevi, Gilead Science Inc)
Pharmacology: A fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor.
Indication: Treatment of adult patients with chronic hepatitis C virus (HCV) with or without compensated cirrhosis.
Adverse Drug Reactions: Headache, fatigue, diarrhea, and nausea.
Dose: One tablet (fixed dose combination of 400 mg of sofosbuvir, 100 mg of velpatasvir and 100 mg of voxilaprevir) for 12 weeks.

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Sofosbuvir; Velpatasvir; Voxilaprevir (Vosevi, Gilead Science INC) (continued)
Formulation: Fixed dose combination of 400 mg of sofosbuvir, 100 mg of velpatasvir and 100 mg of voxilaprevir oral tablets.
Warnings/Contraindications: Risk of Hepatitis B virus reactivation, bradycardia with amiodarone coadministration.
Notes: This combination product is contraindicated with rifampin.

Belimumab (Benlysta Glaxosmithkline LLC)
Pharmacology: B-lymphocyte stimulator specific inhibitor.
Indication: Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.
Adverse Drug Reactions: Nausea, diarrhea, pyrexia, nasopharyngitis, and injection site reactions.
Dose: Intravenous dose- 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Reconstitute, dilute, and administer as an intravenous infusion over 1 hour. Subcutaneous dose- 200 mg once weekly.
Formulation: Intravenous- 120 mg or 400 mg lyophilized powder in single-dose vials for reconstitution and dilution prior to intravenous infusion. Subcutaneous- 200 mg/mL single-dose prefilled autoinjector or single-dose prefilled syringe.
Warnings/Contraindications: Mortality, serious infections, progressive multifocal leukoencephalopathy (PML), hypersensitivity, depression.
Notes: Avoid live vaccines while taking this combination product.

NEW DRUG FORMULATIONS

L-Glutamine (Endari Emmaus Medcl)
Pharmacology: Amino acid.
Indication: To reduce the acute complications of sickle cell disease in patients 5 years old and up.
Dosage form: Oral powder in a paper-foil-plastic laminate packet.
Dose: 5 grams to 15 grams orally twice daily based on weight, mixed with food or beverage.

Nitisinone (Nityr, Cycle Pharms LTD)
Pharmacology: Hydroxyphenyl-pyruvate dioxygenase inhibitor.
Indication: Treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.
Dosage form: 2-mg, 5-mg, and 10-mg oral tablet.
Dose: 0.5 mg/kg orally twice daily, maximum dosage is 1 mg/kg orally twice daily.

Omeprazole (Omeprazole, Dexcel Pharma)
Pharmacology: Proton-pump inhibitor.
Indication: Treatment of gastroesophageal reflux disease, peptic ulcer disease, Zollinger-Ellison syndrome. Prevention of gastrointestinal bleeding.
Dosage form: Extended-release, orally disintegrating tablets.
Dose: 20 mg once daily.

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New drug approvals, formulations, and indications. *New Drug Fax Sheet.* 2017 August 21;22(8):1-2.