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

Lutetium Lu 177 dotatate (Lutathera, Advanced Accelerator Applications)

Pharmacology: Radiolabeled somatostatin analog.

Indication: Treatment of somatostatin receptor-positive gastroenteropancreatic, including foregut, midgut, and hindgut, neuroendocrine (GEP-NETs) tumors in adults.

Adverse Drug Reactions: Lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia, and hypokalemia.

Dose: Recommended dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses.

Formulation: Injection for intravenous use containing 370 MBq/mL (10 mCi/mL) in a single dose vial.

Warnings/Contraindications: Risk from radiation exposure, myelosuppression, secondary myelodysplastic syndrome (MDS) and leukemia, renal toxicity, hepatotoxicity, neuroendocrine hormonal crisis, embryo-fetal toxicity, and risk of infertility.

Notes: Advise patients to urinate frequently during and after administration. Discontinue long-acting analogs for at least 4 weeks and short acting octreotide at least 24 hours prior to each Lutetium Lu 177 dotatate dose. Lactating patients advised not to breastfeed. Verify pregnancy status of females of reproductive potential prior to initiating Lutetium Lu 177 dotatate.

NEW DRUG FORMULATIONS

Levonorgestrel and ethinyl estradiol and ferrous bisglycinate (Balcoltra, Neuvosyn Laboratories LLC)

Pharmacology: Progestin/estrogen combination oral contraceptive (COC).

Indication: For use by females of reproductive potential to prevent pregnancy.

Dosage form: Consists of 28 tablets in the following order: 21 orange tablets (active), each containing 0.10 mg levonorgestrel and 0.02 mg ethinyl estradiol, and 7 blue tablets (inactive placebo) each containing 36.5 mg ferrous bisglycinate.

Dose: Take 1 tablet by mouth at the same time every day following the order as indicated on the blister pack.

Metoprolol succinate (Metoprolol succinate, Sun Pharm Industries)

Pharmacology: $Beta_1$-selective adrenoceptor blocking agent.

Indication: Treatment of hypertension, angina pectoris, and heart failure.

Dosage form: Extended-release capsules 25 mg, 50 mg, 100 mg and 200 mg.

Dose: Dependent upon indication; Usual initial doseage is 25 to 100 mg once daily. Titrate weekly based on clinical response.

Vancomycin hydrochloride (Firvanq, RXM Therapeutics LLC)

Pharmacology: Glycopeptide antibacterial.

Indication: Treatment of *Clostridium difficile*-associated diarrhea (CDAD), enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) in adults and pediatric patients less than 18 years of age.

Dosage form: Kit that contains: vancomycin hydrochloride USP, powder for oral solution, equivalent to 3.75 g, 7.5 g, 10.5 g or 15 g vancomycin, and grape-flavored diluent.

Dose: CDAD in adults: 125 mg by mouth four times daily for 10 days; Enterocolitis in adults: 500 mg to 2 g by mouth in 3-4 divided doses for 7-10 days; Pediatric dosing for CDAD and enterocolitis: 40 mg/kg in 3-4 divided doses for 7-10 days, not to exceed a total daily dose of 2 g.

Atropine sulfate (Atropine sulfate, Fresenius Kabi USA)

Pharmacology: Muscarinic antagonist.

Indication: Temporary blockade of severe or life threatening muscarinic effects e.g., as an antisialagogue, an antivagal agent, an antidote for organophosphorus, carbamate, or muscarinic mushroom poisoning, and to treat symptomatic bradycardia.

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Atropine sulfate (Atropine sulfate, Fresenius Kabi USA) (continued)

Dosage form: Solution for injection for intravenous, intramuscular, subcutaneous, intraosseous or endotracheal use, 8 mg/20 mL (0.4 mg/mL) in a multiple dose vial.

Dose: Individualized by use, dose can range from 0.5 mg to 6 mg depending on indication and route of administration with a maximum total dose of 3 mg for symptomatic bradycardia or antisialagogue or other antivagal use.

Tigecycline (Tigecycline, Accord Hxlthcare INC)

Pharmacology: Tetracycline class antibacterial.

Indication: Treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia in adult patients. (Not indicated for treatment of diabetic foot infection or hospital-acquired pneumonia, including ventilator-associated pneumonia)

Dosage form: For injection: 50 mg, lyophilized powder for reconstitution in a single-dose vial.

Dose: Initial dose of 100 mg, followed by 50 mg every 12 hours administered intravenously over approximately 30 to 60 minutes.

NEW DRUG INDICATIONS

Olaparib (Lynparza, AstraZeneca Pharmaceuticals LP)

Pharmacology: Poly (ADP-ribose) polymerase (PARP) inhibitor.

New Indication: Treatment of patients with deleterious or suspected deleterious germline breast cancer (*gBRCAm*) susceptibility gene, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer, who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR) –positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. Select patients for therapy based on an FDA-approved companion diagnostic for Olaparib.

Dose: Recommended dose is 300 mg (two 150 mg tablets) taken orally twice daily, with or without food, for a total daily dose of 600 mg.

Plecanatide (Trulance, Synergy Pharms)

Pharmacology: Guanylate cyclase-C agonist.

New Indication: Treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

Dose: 3 mg taken orally once daily, with or without food.

Nivolumab (Opdivo, Bristol Myers Squibb)

Pharmacology: Programmed death receptor-1 (PD-1) blocking antibody.

New Indication: Adjuvant therapy in patients with completely resected melanoma with lymph node involvement or metastatic disease.

Dose: 240 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

Afatinib (Gilotrif, Boehringer Ingelheim)

Pharmacology: Kinase inhibitor.

New Indication: To include treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.

Dose: 40 mg orally, once daily at least 1 hour before or 2 hours after a meal.

Influenza virus vaccine, inactivated (Fluarix Quadrivalent, GlaxoSmithKline)

Pharmacology: Influenza virus vaccine.

New Indication: Expanded indication for persons 6 months and older.

Dose: For persons 6 months to 8 years not previously vaccinated or history unknown, or if given <2 doses of trivalent or quadrivalent influenza vaccine before July 1 of current season, give 2 doses of 0.5 mL intramuscularly administered ≥4 weeks apart. Otherwise, give 1 dose of 0.5 mL intramuscularly.

Denosumab (Xgeva, Amgen)

Pharmacology: RANK ligand (RANKL) inhibitor.

New Indication: Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

Dose: 120 mg every 4 weeks as a subcutaneous injection only, in the upper arm, upper thigh, or abdomen.