SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

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 Samford University Global Drug Information Service at (205) 726-2659.

NEW DRUG APPROVALS

Edoxaban (Savaysa, Daiichi Sankyo)

Pharmacology: Factor Xa inhibitor.

Indication: Reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant.

Adverse Drug Reactions: NVAF-bleeding, anemia. DVT/PE – bleeding, rash, abnormal liver function tests, and anemia.

Dose: NVAF-60 mg once daily in patients with CrCL >50 to ≤95 mL/min. Reduce dose to 30 mg once daily in patients with CrCL 15 to 50 mL/min). DVT/PE-60 mg once daily; reduce dose to 30 mg daily for patients with CrCL 15-50 mL/min or body weight ≤60 kg or who use certain P-gp inhibitors.

Formulation: 15-, 30-, and 60-mg tablets.

Warnings/Contraindications: Serious and potentially fatal bleeding may occur. Do not use in patients with mechanical heart valves or those with moderate to severe mitral stenosis.

Notes: Avoid concomitant use with rifampin. No dosage reduction is recommended for concomitant P-gp inhibitors.

Palbociclib (Ibrance, Pfizer Inc.)

Pharmacology: Kinase inhibitor.

Indication: Used in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.

Adverse Drug Reactions: (incidence ≥10%) were neutropenia, leukopenia, fatigue, anemia, upper respiratory infection, nausea, stomatitis, alopecia, diarrhea, thrombocytopenia, decreased appetite, vomiting, asthenia, peripheral neuropathy, and epistaxis.

Dose: The starting dose is 125 mg once daily taken with food for 21 days followed by 7 days off treatment in combination with letrozole.

Formulation: Capsules: 125 mg, 100 mg, and 75 mg.

Warnings/Contraindications: No contraindications. Neutropenia may occur. Monitor complete blood count before staring treatment and at the beginning of each cycle as well as Day 14 of the first two cycles. Monitor for signs and symptoms of infection. Contraception must be used due to potential embryo-fetal toxicity.

Notes: Avoid concurrent use with strong CYP3A inhibitors or moderate to strong CYP3A inducers. The dose of other CYP3A substrates may need to be adjusted if administered concurrently with palbociclib.

NEW BIOLOGIC APPROVALS

Secukinumab (Cosentyx, Novartis Pharms Corp)

Pharmacology: Human interleukin-IL-17A antagonist.

Indication: Treatment of moderate to severe plaque psoriasis in patients with are candidates for systemic therapy or phototherapy.

Adverse Drug Reactions: Nasopharyngitis, diarrhea, and upper respiratory tract infection.

Dose: 300 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4, then 300 mg every 4 weeks. A dose of 150 mg may be acceptable for some patients.

Formulation: Injection: 150 mg/mL solution in a single-use Sensoready® pen; 150 mg/mL solution in a single-use prefilled syringe. Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution.

Warnings/Contraindications: Infections, tuberculosis, Crohn's disease exacerbations, and hypersensitivity reactions.

Notes: Do not administer live vaccines with secukinumab.

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Parathyroid hormone (Natpara, NPS Pharms, Inc)
Pharmacology: Parathyroid hormone.
Indication: Adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.
Adverse Drug Reactions: Paresthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoaesthesia, diarrhea, vomiting, arthralgia, hypercalciuria and pain in extremity.
Dose: Dosing should be individualized. Typical starting is 50 mcg injected once daily in the thigh. Monitor serum calcium levels every 3-7 days after starting or adjusting the dose.
Formulation: Injection: 25 mcg, 50 mcg, 75 mcg, or 100 mcg.
Warnings/Contraindications: Potential risk of osteosarcoma, severe hypercalcemia/hypocalcemia, digoxin toxicity.
Notes: No dosage adjustments needed in patients ≥65 years or in patients with mild to moderate renal or hepatic impairment. Natpara is only available through a restricted program (Natpara REMS).

Group B Meningitis Vaccine (Bexsero, Novartis)
Pharmacology: Contains four recombinant protein strains derived from *N. meningitides.*
Indication: Active immunization to prevent invasive disease caused by *N. meningitidis* serogroup B. Bexsero is approved for use in individuals 10 through 25 years of age.
Adverse Drug Reactions: The most common solicited adverse reactions observed in clinical trials were pain at the injection site (≥83%), myalgia (≥48%), erythema (≥45%), fatigue (≥35%), headache (≥33%), induration (≥ 28%), nausea (≥18%), and arthralgia (≥13%).
Dose: Administer one dose (0.5 mL) intramuscularly (IM) followed by a second dose 1 month later.
Formulation: Suspension for IM injection in 0.5 mL single-dose pre-filled syringes.
Warnings/Contraindications: Hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose.
Notes: The tip caps of the pre-filled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

NEW DRUG FORMULATIONS AND COMBINATIONS

Carbidopa/Levodopa (Rytary, Impax Labs)
Pharmacology: Carbidopa/levodopa combination.
Indication: Treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.
Dosage form: Carbodopa/levodopa extended-release capsules-23.75 mg / 95 mg; 36.25 mg/145 mg; 48.75 mg / 195 mg; 61/25 mg/245 mg.
Dose: Starting dose is 23.75 mg/95 mg three times daily; may increase to 36.25 mg/145 mg three times daily on the fourth day of treatment.

Phoxillum (Gambro Lundia AB)
Pharmacology: Electrolyte solutions.
Indication: Replacement solution in continuous renal replacement therapy (CRRT) and in case of drug poisoning when CRRT is used to remove dialyzable substances.
Dosage form: Multiple variations of strengths.
Dose: Multiple.

Ferric Pyrophosphate Citrate (Triferic, Rockwell Medcl)
Pharmacology: Iron.
Indication: Replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).
Dosage form: Ampule: 27.2 mg of iron (III) per 5 mL (5.44 mg of iron (III) per mL).
Dose: Final hemodialysate concentration of 110 mcg/L.

Neostigmine Methylsulfate (Methylsulfate, Fresenius Kabi USA)
Pharmacology: Competitive cholinesterase inhibitor.
Indication: Reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBA) after surgery.
Dosage form: Injection: 0.5 mg/mL and 1 mg/mL solution in 10 mL multiple dose vial in packages of 10 vials.
Dose: Recommended dosage range is 0.03 mg/kg to 0.07 mg/kg for reversing non-depolarizing neuromuscular block when administered with an anticholinergic agent (atropine or glycopyrrolate).

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Carbidopa/Levodopa (Duopa, Abbvie Inc)
Pharmacology: Carbidopa/Levodopa combination.
Indication: Treatment of motor fluctuations in patients with advanced Parkinson's disease.
Dosage form: Enteral suspension: 4.63 mg carbidopa and 20 mg levodopa per mL.
Dose: Maximum recommended dose is 2000 mg of levodopa (i.e., one cassette per day) administered over 16 hours.

Perindopril arginine; amlodipine besylate (Prestalia, Symplmed Pharms, LLC)
Pharmacology: Angiotensin converting enzyme inhibitor / dihydropyridine calcium channel blocker.
Indication: Treatment of hypertension in patients not adequately controlled with monotherapy and in patients who require multiple drugs to achieve their blood pressure goals.
Dosage form: Tablets (perindopril arginine/amlodipine) - 3.5/2.5 mg; 7/5 mg and 14/10 mg.
Dose: Initial treatment-3.5/2.5 mg once daily.

Darunavir/Cobicistat (Prezcobix, Janssen Prods)
Pharmacology: Protease / CYP3A inhibitor.
Indication: Treatment of HIV-1 viral infection.
Dosage form: Tablets – darunavir 800 mg; cobicistat 150 mg.
Dose: One tablet taken daily once daily with food.

Atazanavir / Cobicistat (Evotaz, Bristol Myers Squibb)
Pharmacology: Protease / CYP3A inhibitor.
Indication: Treatment of HIV-1 viral infection.
Dosage form: Tablets – atazanavir 300 mg; cobicistat 150 mg.
Dose: One tablet once daily, taken orally with food.

Empagliflozin / Linagliptin (Glyxambi, Boehringer Ingelheim)
Pharmacology: Sodium-glucose co-transporter 2 (SGLT2) inhibitor and dipeptidyl peptidase-4 (DDP-4) inhibitor.
Indication: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dosage form: Tablets: empagliflozin/linagliptin-10 mg/ 5 mg; 25 mg / 5 mg.
Dose: Recommended dose is empagliflozin/linagliptin-10 mg/ 5 mg once daily; taken in the morning with or without food.

Lamivudine / Raltegravir (Dutrebis, Merck Sharp Dohme)
Pharmacology: combination of an HIV-1 nucleoside analogue reverse transcriptase inhibitor (NRTI) and an integrase strand transfer inhibitor.
Indication: in combination with other antiretroviral agents for the treatment of HIV-1 infection.
Dose: Adults, adolescents (16 years of age and older), and pediatric patients (6 through 16 years of age and weighing at least 30 kg): 150 mg lamivudine/300 mg raltegravir tablet orally twice daily with or without food.
Formulation: Tablets: 150 mg lamivudine and 325.8 mg raltegravir potassium (equivalent to 300 mg raltegravir).

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