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

Nivolumab (Opdivo, Bristol Myers Squibb)

Pharmacology: Programmed death receptor-1 (PD-1).
Indication: Treatment of patients with the following: unresectable or metastatic melanoma and disease progression following ipilumumab and BRAF V600 mutation positive, a BRAF inhibitor and metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy.
Adverse Drug Reactions: Most common reaction was rash (≥20), fatigue, dyspnea, musculoskeletal pain, decreased appetite, cough, nausea, and constipation.
Dose: 3 mg/kg as an intravenous infusion over 60 minutes every 2 weeks.
Formulation: Injection: 40 mg/4 mL and 100 mg/10 mL solution in a single-use vial.
Warnings/Contraindications: Immune mediated adverse reactions including (pneumonitis, colitis, hepatitis, nephritis and renal dysfunction, hypo/hyperthryroidism, embryofetal toxicity).
Notes: Discontinue therapy in patients with creatinine > 1.5 and up to 6 times ULN or greater than 1.5 times baseline.

Isavuconazonium Sulfate (Cresemba, Astellas)

Pharmacology: Azole antifungal.
Indication: Treatment of invasive aspergillosis, and mucormycosis.
Adverse Drug Reactions: Nausea, vomiting, diarrhea, headache, elevated liver chemistry test, hypokalemia, constipation dyspnea, cough, peripheral edema, and back pain.
Dose: Loading dose: 372 mg isvuconazonium sulfate every 8 hours for 6 doses; maintenance dose: 372 mg isavuconazonium once daily starting 12-24 hours after the loading dose.
Formulation: Capsules 186 mg isavuconazonium sulfate; 372 mg isavuconazonium injection.
Warnings/Contraindications: Hypersensitivity; coadministration with strong CYP3A4 inhibitors, coadministration with strong CYP3A4 inducers, and in patients with familial short QT syndrome.
Notes: Must be administered via an in-line filter.

Cholic acid (Cholbam, Asklepion Pharmaceuticals, LLC)

Pharmacology: Bile acid.
Indication: Treatment of bile acid synthesis disorders due to single enzymes defects and adjunctive treatment of peroxisomal disorder (PDs).
Adverse Drug Reactions: Diarrhea, reflux, esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy.
Dose: Dosing varies based on indication.
Formulation: Capsules, 50 mg, 250 mg.
Warnings/Contraindications: Exacerbation of liver impairment.
Notes: Avoid bile salt efflux pump inhibitors (e.g., cyclosporine). Take cholic acid at least 1 hour before or 4-6 hours after bile acid binding resin or aluminum-based antacids.

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Dinutuximab (Unituxin, United Therapeutics)
Pharmacology: GD2-binding monoclonal antibody.
Indication: Treatment of pediatric patients with high-risk neuroblastoma, in combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 12-cis-retonoic acid, who achieve at least a partial response to prior first-line multiagent, multimodality therapy.
Adverse Drug Reactions: Pain, pyrexia, thrombocytopenia, lyphophenia, infusion reactions, hypotension, hyponatremia, increased alanine aminotransferase, anemia, vomiting, diarrhea, hypokalemia, capillary leak syndrome, neutropenia, urticarial, hypoalbuminemia, increased aspartate aminotransferase, and hypocalcemia.
Dose: 17.5 mg/m^2/day as a diluted intravenous infusion over 10 to 20 hours for 4 consecutive days for up to 5 cycles.
Formulation: Injection: 17.5 mg/5mL (3.5 mg/mL) in a single-use vial.
Warnings/Contraindications: Serious infusion reactions and neuropathy.
Notes: Store vials in a refrigerator.

Filgrastim-SNDZ (Zarxio, Sandoz Pharmaceuticals)
Pharmacology: Leukocyte growth factor.
Indication: Decrease incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer agents; reduce time to neutrophil recovery and duration of fever following chemotherapy for acute myeloid leukemia (AML), reduce duration of neutropenia and neutropenia-related clinical sequelae, mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, reduce the incidence and duration of sequelae of severe neutropenia.
Adverse Drug Reactions: Pyrexia, pain, rash, cough, dyspnea, headache, diarrhea, alopecia.
Dose: Varies based on indication.
Formulation: Injection: 300 mcg/0.5 mL in a single-use prefilled syringe or 480 mcg/0.8 mL in single-use prefilled syringe.
Warnings/Contraindications: Fatal splenic rupture, acute respiratory distress syndrome; serious allergic reactions; fatal sickle cell crisis.
Notes: Do not dilute with saline or the product may precipitate.

Anthrax Immune Globulin Intravenous (Human) (Anthrasil, Emergent BioSolutions)
Pharmacology:
Indication: Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.
Adverse Drug Reactions:
Dose: Adults (≥17 years)-7 vials (420 units) administered at 0.5 mL/min over the first 30 minutes, then 1 mL/min every 30 minutes (maximum infusion rate is 2 mL/min). Pediatric patients (<1 year to ≤16 years): 1-7 vials (60-420 units) based on patient weight. The starting infusion rate is 0.01 mL/kg/min during the first 30 minutes, then 0.04 mL/kg/min. The adult infusion rate should not be exceeded.
Formulation: ≥60units by Toxin Neutralization Assay (TNA) in each single-use vial.
Warnings/Contraindications: Hypersensitivity, thrombus formation, reduced renal function, hemolysis / hemolytic anemia, aseptic meningitis syndrome, transfusion-related acute lung injury, and transmission of infectious agents from human plasma.
Notes: Product interferes with blood and urine glucose testing.

NEW DRUG FORMULATIONS

Levetiracetam (Elepsia XR, Sun Pharma Advanced Research Co, LTD)
Pharmacology: Anticonvulsant, miscellaneous.
Indication: Adjunctive therapy in the treatment of partial onset seizures in patients ≥ 12 years of age with epilepsy.
Dosage form: Extended-release tables: 1000 mg, 1500 mg.
Dose: Initial: 1000 mg once daily (maximum dose is 3,000 mg once daily).

Argatroban injection (Argatroban, Fresenius Kabi, USA)
Pharmacology: Direct thrombin inhibitor.
Indication: Prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) or as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention.
Dosage form: 250 mg per 2.5 mL (200 mg/mL) in a single-dose vial.
Dose: Based on indication.

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Deferasirox (Jadenu, Novartis Pharms Corp)
Pharmacology: Iron chelator.
Indication: Chronic iron overload due to blood transfusions in patients 2 years of age and older.
Dosage form: Tablets: 90 mg, 180 mg, 360 mg.
Dose: Varies based on indication.

Ivacaftor (Kalydeco, Vertex Pharms)
Pharmacology: Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator.
Indication: Treatment of cystic fibrosis (CF) in patients age 2 years and older with a mutation on CFTR gene.
Dosage form: Tablets: 150 mg; oral granules: unit-dose packets of 50 mg and 75 mg.
Dose: Dosage varies based on indication and population.

NEW DRUG INDICATIONS

Asenapine (Saphris, Actavis)
Pharmacology: Atypical antipsychotic.
Indication: Manic or mixed episodes associated with bipolar I disorder in pediatric patients.
Dosage form: Sublingual tablets, black cherry flavor: 2.5 mg, 5 mg, and 10 mg.
Dose: Initial dosage: 2.5 mg sublingually twice daily.

Aflibercept (Eylea, Regeneron Pharmaceuticals)
Pharmacology: Recombinant fusion protein.
Indication: Diabetic retinopathy in patients with diabetic macular edema.
Dosage form: 40 mg/mL solution for intravitreal injection.
Dose: 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).

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