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

Edaravone (Radicava, Mitsubishi Tanabe Pharma Development America, Inc.)

Pharmacology: An intravenous antioxidant.
Indication: Treatment of Amyotrophic Lateral Sclerosis (ALS).
Adverse Drug Reactions: Hypersensitivity reactions and sulfite allergic reactions, contusion, gait disturbance, and headache.
Dose: The recommended dose is 60 mg administered as an intravenous infusion over 60 minutes as follows: (1) initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period; (2) subsequent treatments cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.
Formulation: Injection: 30 mg/100mL in a single-dose polypropylene bag.
Warnings/Contraindications: Hypersensitivity reactions and anaphylactic cases have been reported in spontaneous postmarketing reports; sulfite allergic reactions.
Notes: Edaravone contains sodium bisulfite, that may cause a type of allergic reaction that can be serious and life-threatening or can be less severe (i.e., asthmatic-like episode). Sulfite allergic reactions can happen more often in people who have asthma than in those who do not have asthma.

Durvalumab (Imfinzi, AstraZeneca Pharmaceutical LP)

Pharmacology: Human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that blocks the interaction of programmed death-ligand 1 (PD-L1) with PD-1 and CD80 molecules.
Indication: Treatment of patients with locally advanced or metastatic urothelial carcinoa; who have disease progression during or following platinum-containing chemotherapy; or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
Adverse Drug Reactions: Fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral edema, and urinary tract infection.
Dose: Administer 10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks. Dilute prior to infusing.
Formulation: Injection: 500 mg/10mL solution in a single-dose vial and 120 mg/2.4mL solution in a single-dose vial.
Warnings/Contraindications: Immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies (e.g., Type 1 Diabetes Mellitus, adrenal insufficiency or hypophysitis), immune-mediated nephritis, immune-mediated rash or purura, infection, infusion-related reactions, and embryo-fetal toxicity.
Notes: The drug should be permanently discontinued if patients experience a grade 4 adverse drug reaction.

Sarilumab (Kevzara, Sanofi-Aventis U.S. LLC)

Pharmacology: An interleukin-6 (IL-6) receptor antagonist.
Indication: Treatment of adult patients with moderate-to-severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDS).
Adverse Drug Reactions: Neutropenia, increased ALT, injection site erythema, upper respiratory tract infections, and urinary tract infections.
Dose: A total of 200 mg once every 2 weeks administered as a subcutaneous injection. It may be used as monotherapy or in combination with methotrexate or other conventional DMARDs.
Formulation: Injection: 150 mg/1.14mL or 200 mg/1.14mL solution in a single-dose pre-filled syringe.
Warnings/Contraindications: Risk of serious infections (avoid use during an active infection), neutropenia, thrombocytopenia, elevated liver enzymes, lipid abnormalities, GI perforation risk increased with concurrent diverticulitis or concomitant use of NSAIDs or corticosteroids, hypersensitivity reactions, and avoid use of live vaccines with sarilumab due to the risk of infection.
Notes: Caution should be administered when coadministering sarilumab with CYP3A4 substrates.

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Avelumab (Bavencio, EMD Serono, Inc.)
Pharmacology: Programmed death ligand-1 (PD-L1) blocking antibody.
Indication: Treatment of adult and pediatric patients ≥12 years of age with metastatic Merkel cell carcinoma (MCC).
Adverse Drug Reactions: Fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reactions, rash, decreased appetite, and urinary tract infections.
Dose: Administer 10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks.
Formulation: Injection: 200 mg/10mL solution in a single-dose vial.
Warnings/Contraindications: Immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies, immune-mediated nephritis and renal dysfunction, infusion-related reactions, Stevens-Johnson Syndrome/Toxic epidermal necrolysis, and embryo-fetal toxicity.
Notes: Premedicate for the first 4 infusions and subsequently as needed.

NEW DRUG FORMULATIONS

Ribociclib tablets; Letrozole tablets (Kisqali Femara Co-Pack, Novartis Pharms Corp.)
Pharmacology: Ribociclib is a kinase inhibitor and letrozole is an aromatase inhibitor.
Indication: The initial treatment of endocrine-based therapy for postmenopausal women with hormone-receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
Dosage form: Tablets (co-packaged): Ribociclib: 200 mg; Letrozole: 2.5 mg.
Dose: Tablets are taken in combination with or without food. Ribociclib starting dose: 600 mg orally (three 200 mg tabs) once daily for 21 consecutive days followed by 7 days off Ribociclib treatment. Letrozole dose: 2.5 mg (1 tab) continuously for a 28-day cycle.

Deferasirox (Jadenu Sprinkle, Novartis Pharms Corp.)
Pharmacology: An iron chelator.
Indication: Treatment of chronic iron overload due to blood transfusions in patients ≥ 2 years of age and for the treatment of chronic iron overload in patients ≥10 years of age with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration of at least 5 mg Fe per gram of dry weight (F/g dw) and a serum ferritin greater than 300 mcg/L.
Dosage form: Granules: 90 mg, 180 mg, 360 mg.
Dose: For transfusional iron overload: initial dose of 14 mg/kg (calculated to nearest whole packet content of granules) once daily. For NTDT syndromes: initial dose of 7 mg/kg (calculated to nearest whole packet content of granules) once daily.

Talc (Steritalc, Novatech SA)
Pharmacology: A sclerosing agent.
Indication: To decrease the recurrence of malignant pleural effusions in symptomatic patients following maximum drainage of the pleural effusion and to decrease the recurrence of pneumothorax in adults.
Dosage form: Powder: 2 grams in a 50mL single-dose vial, 4 grams in a 50mL single-dose vial, and 3 grams in a 10mL single-dose vial.
Dose: Malignant pleural effusion: 2-5 grams administered intrapleurally; Pneumothorax: 2 grams administered intrapleurally. Do not exceed a total cumulative dosage of 10 grams per procedure.

Cetirizine Ophthlamic Solution (Zerviate 0.24%, Akorn Inc.)
Pharmacology: A histamine-1 receptor antagonist.
Indication: For ocular itching associated with allergic conjunctivitis.
Dosage form: Ophthalmic Solution: 2.4 mg cetirizine in 1 mL sterile solution (0.24%).
Dose: One drop in each affected eye twice daily.

NEW DRUG INDICATIONS

Ivacafort (Kalydeco, Vertex Pharmaceuticals Inc.)
Pharmacology: A cystic fibrosis transmembrane conductance regulator (CFTR) potentiator
New Indication: The treatment of cystic fibrosis in patients 2 years of age and older who have one mutation in the CFTR gene that is responsive to ivacafort based on clinical and/or in vitro assay data.
Dose: Adults and children ≥ 6 years old: one 150mg tablet orally every 12 hours with a fat-containing meal; Children 2 to <6 years old weighing < 14kg: take one 50 mg packet mixed with 5mL of soft food or liquid and administered orally every 12 hours with fat-containing meal; Children 2 to <6 years old weighing ≥ 14kg: take one 75 mg packet mixed with 5mL of soft food or liquid and administered orally every 12 hours with fat-containing meal.