CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY SAMFORD UNIVERSITY
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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

Coagulation Factor IA (Recombinant), Albumin Fusion Protein (rIX-FP) (Idelvion, CSL Behring LLC)
Pharmacology: Recombinant human blood coagulation factor.
Indication: Children and adults with hemophilia B (congenital Factor IX deficiency for on-demand control and prevention of bleeding episodes; perioperative management of bleeding; and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
Adverse Drug Reactions: Headache.
Dose: Dose id dependent upon severity of Factor IX deficiency, location and extent of bleeding and patient-related factors.
Formulation: Single-use vials containing nominally 250, 500, 1000 or 2000 IU.
Warnings/Contraindications: Hypersensitivity reactions; development of neutralizing antibodies, thromboembolism, and nephrotic syndrome.
Notes: Higher dose per kg body weight or more frequent dosing may be needed for pediatric patients.

Ixekizumab (Taltz, Eli Lilly and Company)
Pharmacology: Humanized interleukin-17A antagonist.
Indication: Treatment of moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Adverse Drug Reactions: Injection site reactions, upper respiratory tract infections, nausea, and tinea infections.
Dose: 160 mg (two 80 mg injections at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, 12, then 80 mg every 4 weeks.
Formulation: Autoinjector and prefilled syringe containing 80 mg/mL;
Warnings/Contraindications: Serious infections, evaluate for TB prior to initiating treatment, hypersensitivity, and inflammatory bowel disease.
Notes: Live vaccines should not be given with ixekizumab.

Reslizumab (Cinqair, Teva Pharmaceuticals)
Pharmacology: Interleukin-5 antagonist monoclonal antibody (IgG4 kappa).
Indication: Add-on maintenance treatment of patients with severe eosinophilic phenotype asthma.
Adverse Drug Reactions: Oropharyngeal pain.
Dose: 3mg/kg once every 4 weeks by intravenous infusion over 20-50 minutes.
Formulation: Injection: 100 mg/10 mg (10 mg/mL) solution in single-use vials.
Warnings/Contraindications: Malignancy, reduction in corticosteroid dosage, parasitic (helminth) infection.
Notes: Reslizumab is not indicated for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

Defibrotide sodium (Defitelio, Jazz Pharmaceuticals)
Pharmacology: Enhances the enzymatic activity of plasmin to hydrolyze fibrin clots.
Indication: Treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation.
Adverse Drug Reactions: Hypotension, diarrhea, vomiting, nausea, and epistaxis.
Dose: 6.25 mg/kg every 6 hours given as a 2-hour intravenous infusion. Treat a minimum of 21 days. After 21 days, continue treatment until resolution.
Formulation: Single patient-use vial: 200 mg/2.5 ml (80 mg/mL) injection.
Warnings/Contraindications: Hemorrhage, hypersensitivity reactions.
Notes: Defibrotide may enhance the activity of antithrombotic/fibrinolytic drugs.

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NEW DRUG APPROVALS (CONTINUED)

Obiltoxaximab (Anthim, Elusys Therapeutics, Inc.)
Pharmacology: Monoclonal antibody directed against the protective antigen of *Bacillus anthracis.*
Indication: Treatment of adult and pediatric patients with inhalation anthrax due to *B. anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalation anthrax when alternative therapies are not available or appropriate.
Adverse Drug Reactions: Headache, pruritus, infections of the upper respiratory tract, cough, vessel puncture site bruise, infusion site swelling, nasal congestion, infusion site pain, urticaria, and pain in extremity.
Dose: Adults: 16 mg/kg; pediatric patients: ≥40 kg: 16 mg/kg; ≥15-40 kg: 24 mg/kg; ≤15 kg: 32 mg/kg.
Formulation: Injection: 600 mg/mL single-use vials.
Warnings/Contraindications: Hemorrhage, hypersensitivity reactions.
Notes: No studies of the safety or pharmacokinetic of obiltoxaximab have been conducted in the pediatric population.

NEW DRUG FORMULATIONS

Emtricitamine, rilpivirine, and tenofovir alafenamide (Odefsey, Gilead Sciences, Inc.)
Pharmacology: HIV nucleoside analog reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NRTI), and a non-nucleoside reverse transcriptase inhibitor (NNRTI).
Indication: Treatment of HIV-1 infection in patients with no antiretroviral treatment history with HIV-1 RNA ≤1000,000 copies per mL or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) for at least 6 months with no history of treatment failure and no substitutions associated with resistance to the individual components.
Adverse Drug Reactions: Rilpivirine: depressive disorders, insomnia, and headache. Emtricitabine and tenofovir alafenamide: nausea.
Dose: One tablet daily with a meal.
Formulation: Tablets: 200 mg emtricitabine (FTC), 35 mg rilpivirine (RPV), and 25 mg tenofovir alafenamide (TAF).
Warnings/Contraindications: Contraindicated when coadministered with drugs that may result in significant decreases in RPV plasma concentrations.

NEW DRUG INDICATIONS

Ibrutinib (Imbruvica, Janssen Biotech and Parmacyclics, Inc)
Pharmacology: Kinase inhibitor.
Indication: Chronic Lymphocytic Leukemia (CLL).
Dose: 420 mg taken orally once daily (three 140 mg capsules).

Crizotinib (Xalkori, Pfizer)
Pharmacology: Kinase inhibitor.
Indication: Advanced (metastatic) non-small cell lung cancer whose tumors have an ROS-1 gene alteration.
Dose: 250 mg orally twice daily.

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