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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

Latanoprostene (Vzulta, Bausch and Lomb, Inc)

Pharmacology: Prostaglandin Analog..

Indication: Reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Adverse Drug Reactions: Conjunctival hyperemia, eye irritation, pain, and instillation site pain.

Dose: One drop in the affected eye (s) once daily in the evening.

Formulation: Topical ophthalmic solution-0.24 mg/mL.

Warnings/Contraindications: Increased pigmentation, eyelash changes.

Notes: If administering latanoprostene with other ophthalmic agents, administer product at least 5 minutes apart.

Letermovir Prevymis, Merck Sharp Dohme)

Pharmacology: Cytomegalovirus (CMV) DNA terminase complex inhibitor.

Indication: Prophylaxis of cytomegalovirus infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

Adverse Drug Reactions: Nausea, Diarrhea, Vomiting, Peripheral edema, cough, headache, fatigue, and abdominal pain.

Dose: A dose of 480 mg administered once daily orally or as an intravenous (IV) infusion over 1 hour through 100 days post-transplant. The dosage of letermovir should be decreased to 240 mg once daily when coadministered with cyclosporine.

Formulation: Tablet: 240 mg, 480 mg; injection: 240 mg/12 mL or 480 mg/24 mL in a single-dose vial.

Warnings/Contraindications: Letermovir is contraindicated with pimozide, ergot alkaloids, pitavastatin and simvastatin.

Notes: Letermovir use is not recommended in patients with severe hepatic impairment; the serum creatinine levels should be closely monitored in patients with CLcr <50 mL/min.

Benralizumab (Fasenra, Astra Zeneca)

Pharmacology: Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody.

Indication: Add on maintenance treatment of patients with severe asthma, of the eosinophilic phenotype, aged 12 years and older.

Adverse Drug Reactions: Headache, pharyngitis.

Dose: The recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter. All doses are administered by subcutaneous injection.

Formulation: Injection: 30 mg/mL solution.

Warnings/Contraindications: Hypersensitivity reactions, reduction in corticosteroid dosage may be necessary, and treatment of parasitic infections should occur before therapy with benralizumab.

Notes: Systemic or inhaled corticosteroids should not be discontinued abruptly upon initiation of benralizumab.

Vestronidase Alfal-VJBK Mepsevii, Ultragenyx Pharm, Inc)

Pharmacology: Recombinant human lysosomal beta glucuronidase.

Indication: Treatment of mucopolysaccharidosis VII (MPS VII, Sly syndrome) in pediatric and adult patients.

Adverse Drug Reactions: Extravasation, diarrhea, rash, anaphylaxis, infusion site swelling, peripheral swelling, and pruritus.

Dose: The dose is 4 mg/kg administered every 2 weeks as an intravenous infusion.

Formulation: Injection- 10 mg/5 mL in a single-dose vial.

Warnings/Contraindications: Anaphylaxis.

Notes: Premedication is recommended 30-60 minutes prior to the start of the infusion.

Emicizumab (Hemlibra, Genetech, Inc.)

Pharmacology: Bispecific factor IXa- and factor X-directed antibody.

Indication: Prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.

Adverse Drug Reactions: Injection site reactions, headache, and arthralgia.

Dose: The dose is 3 mg/kg, administered as a subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly.

Formulation: Injection available as – 30 mg/mL, 60 mg/0.4 mL; 105 mg/0.7 mL; and 150 mg/mL, as a single-dose vial.

Warnings/Contraindications: Laboratory test interference with blood clotting assays.

Notes: Unopened vials of emicizumab may be stored out of refrigeration and then returned; however, the combined time out of refrigeration should not exceed 30 °C (86 °F) and 7 days (at a temperature below 30 °C (86 °F)).

NEW DRUG FORMULATIONS

Bortezomib (Bortezomib, Fresenius Kabi, USA)

Pharmacology: Proteasome inhibitor.

Indication: Treatment of patients with multiple myeloma. Treatment of mantle cell lymphoma in patients who have received at least 1 prior therapy.

Dosage form: Single-dose vial that contains bortezomib 3.5 mg lyophilized powder for reconstitution.

Dose: The recommended dosage is 1.3 mg/m² administered as a 305 second bolus intravenous injection.

Aprepitant (Cinvanti, Heron Theraps, Inc.)

Pharmacology: Substance P/neurokinin-1 (NK1) receptor antagonist.

Indication: Acute and delayed nausea and vomiting associated with highly or moderately emetogenic cancer chemotherapy.

Dosage form: Injectable emulsion-130 mg aprepitant in single-dose vial.

Dose: The recommended dosage is variable depending on emetogenicity potential of the chemotherapy agent.

Aripiprazole (Abilify Mycite, Otsuka Pharm Co, LTD)

Pharmacology: Aripiprazole combined with an Ingestible Event Marker (IEM) sensor.

Indication: Treatment of adults with schizophrenia, bipolar I disorder, and adjunctive treatment for major depressive disorder.

Dosage form: 2-mg, 5-mg, 10-mg, 15-mg, 20-mg, and 30-mg tablets with sensors.

Dose: Varies depending on indication.

Palonosetron (Palonosetron, Fresenius Kabi, USA)

Pharmacology: Serotonin-3 (5-HT₃) receptor antagonist.

Indication: Prevention of acute and delayed nausea and vomiting for moderately/highly emetogenic cancer chemotherapy. Prevention of postoperative nausea and vomiting for up to 24 hours after surgery.

Dosage form: Injection 0.25/5 mL single-dose via or pre-filled syringe.

Dose: The dose is 0.25 mg.

Dolutegravir; Rilpivirine (Juluca, VIV Healthcare)

Pharmacology: Two drug combination of dolutegravir (HIV-1 integrase transfer inhibitor [INSTI]) and rilpivirine (HIV-1 non nucleoside reverse transcriptase inhibitor [NNRTI]).

Indication: Treatment of HIV-1 infection to replace regimen that resulted in treatment failure.

Dosage form: Tablets containing dolutegravir 50 mg and rilpivirine 25 mg.

Dose: One tablet taken daily with meals.

Clobetasol (Impoiz, Promius Pharma, LLC)

Pharmacology: Corticosteroid.

Indication: Moderate to severe plaque psoriasis in patients 18 years and older.

Dosage form: Cream, 0.025%.

Dose: Thin layer should be applied to the affected areas twice daily for up to 2 weeks.

Sodium picosulfate; Magnesium oxide; Anhydrous citric acid (Clenpiq, Ferring Pharma, LLC)

Pharmacology: Combination of stimulant / osmotic laxative.

Indication: Cleansing of the colon as a preparation for colonoscopy in adults.

Dosage form: Oral solution containing sodium picosulfate 10 mg, magnesium oxide 3.5 g, and anhydrous citric acid 12 g in 160 mL of solution.

Dose: Two doses are required for complete preparation as a split dosage regimen or day before regimen.

Buprenorphine (Sublocade, Indivior, Inc)

Pharmacology: Partial opioid agonist.

Indication: Moderate to severe opioid use disorder.

Dosage form: Injection containing 100 mg/0.5 mL and 300 mg/1.5 mL solution.

Dose: Two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses.

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