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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 (205) 726-2659.

## NEW DRUG APPROVALS

### **Indacaterol and glycopyrronium (Utibron Neohaler, Novartis Pharmaceuticals Corporation)**

**Pharmacology:** Reversible competitive muscarinic receptor inhibitor / Beta<sub>2</sub> agonist local to the lungs.

**Indication:** Chronic Obstructive Pulmonary Disease (COPD).

**Adverse Drug Reactions:** Upper Respiratory Tract Infection (URTI) and nasopharyngitis.

**Dose:** Inhale the contents of one capsule twice daily.

**Formulation:** Indacaterol 27.5 mcg and glycopyrronium 15.6 mcg dry powder capsule for inhalation.

**Warnings/Contraindications:** Increase in asthma related death, bronchospasm, CNS depression, hypersensitivity.

Caution should be used in patients with: Cardiovascular disease, DM, hepatic dysfunction, hypokalemia, BPH, renal dysfunction, hyperthyroidism, narrow angle glaucoma.

**Notes:** Several drug-drug interactions may occur with xanthine derivatives, steroids, diuretics, or non-potassium sparing diuretics that may increase the risk for hypokalemia or ECG changes.

### **Elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (Genvoya, Gilead Sciences, Inc.)**

**Pharmacology:** Antiretroviral (Integrase Inhibitor), Antiretroviral (Reverse Transcriptase Inhibitor, Nucleoside),

Antiretroviral (Reverse Transcriptase Inhibitor, Nucleotide), Cytochrome P-450 Inhibitor.

**Indication:** HIV-1 infection.

**Adverse Drug Reactions:** Fat maldistribution, hypophosphatemia, lactic acidosis, increased cholesterol, increased triglycerides, diarrhea, nausea, hepatitis B exacerbation, hepatomegaly, immune reconstitution syndrome, decreased bone density, bone fractures, increased creatine kinase, renal problems, headache, and fatigue.

**Dose:** For patients 12 and older who weigh at least 35 kg, the dose is one tablet by mouth daily with food.

**Formulation:** Oral tablet consisting of 150 mg elvitegravir, 150 mg cobicistat, 200 mg emtricitabine, and 10 mg tenofovir alafenamide.

**Warnings/Contraindications:** Drugs that are highly dependent on CYP3A4 for clearance and cause problems at elevated plasma concentrations are contraindicated with this drug. Other antiretrovirals are not recommended to be used in a patient on this therapy. Do not use in patients with hepatitis B infection.

**Notes:** Test for hepatitis B infection prior to therapy. If patient has creatinine clearance that is less than 30 mL/min or severe hepatic impairment (Child-Pugh class C) this drug is not recommended.

### **Antihemophilic Factor VIII Recombinant Pegylated (Adynovate, Baxalta US, Inc.)**

**Pharmacology:** Antihemophilic Agent, Hemostatic, Blood Modifier.

**Indication:** Bleeding treatment and prophylaxis for Hemophilia A.

**Adverse Drug Reactions:** Hypersensitivity reactions that may cause hypotension, antibody development, nausea and vomiting, diarrhea, headache, dizziness, injection site reactions, pruritus, rash, hives, and fever.

**Dose:** For prophylaxis, 40 to 50 IU/kg twice a week is used and then is adjusted based on clinical response. For bleeding, dose is individualized based upon how much factor VIII needs to be increased to stop bleeding.

**Formulation:** Powder in 250, 500, 1000, and 2000 IU dosages with diluents for creating solutions. Baxject II Hi-Flow Needleless Transfer Device is designed for easy use at home with these powder formulations.

**Warnings/Contraindications:** Contraindicated in patients with previous anaphylactic reactions to any component of the drug. Do not use if allergic to mice or hamster protein. Also, there have been cases of the development of neutralizing antibodies to factor VIII so monitoring is recommended to ensure effectiveness.

**Notes:** Refrigerate powder between 2 to 8 degrees Celsius. If kept at room temperature, then must be used within one month. Do not refrigerate after leaving out at room temperature. Do not use past expiration date. Store vials in original container and protect from light. Do not refrigerate reconstituted solution and must use within three hours.

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**Cobimetinib (Cotellic, Genetech)**

Pharmacology: Kinase inhibitor.

Indication: Treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutation, in combination with vemurafenib.

Adverse Drug Reactions: Diarrhea, photosensitivity reaction, nausea, pyrexia, and vomiting.

Dose: 60 mg orally, with or without food, once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity develops.

Formulation: 20-mg tablets.

Warnings/Contraindications: new primary malignancies, hemorrhage, cardiomyopathy, severe dermatologic reactions, serous retinopathy and retinal vein occlusion, hepatotoxicity, rhabdomyolysis, severe photosensitivity, and embryo-fetal toxicity.

Notes: Avoid concomitant administration with strong or moderate CYP3A inducers or inhibitors.

**Osimertinib (Tagrisso, AstraZeneca)**

Pharmacology: Kinase inhibitor.

Indication: Treatment of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).

Adverse Drug Reactions: Diarrhea, rash, dry skin, and nail toxicity.

Dose: 80 mg orally, with or without food.

Formulation: 40 and 80-mg tablets.

Warnings/Contraindications: Interstitial lung disease (ILD)/pneumonitis, QTc interval prolongation, cardiomyopathy, and embryo-fetal toxicity.

Notes: Avoid concomitant administration with strong or moderate CYP3A inducers or inhibitors.

**Necitumumab (Portrazza, Eli Lilly)**

Pharmacology: Epidermal growth factor receptor (EGFR) antagonist.

Indication: First-line treatment of metastatic squamous non-small cell lung cancer in combination with gemcitabine and cisplatin.

Adverse Drug Reactions: Rash and hypomagnesemia.

Dose: 800 mg as an intravenous infusion over 60 minutes on days 1 and 8 of each 3-week cycle.

Formulation: 800 mg/50 mL solution in a single-dose vial.

Warnings/Contraindications: Cardiopulmonary arrest, hypomagnesemia, venous and arterial thromboembolic events, dermatologic toxicities, infusion-related reactions, increased toxicity, and embryo-fetal toxicity.

Notes: No dosage adjustment needed for renal or hepatic impairment.

**Influenza vaccine, adjuvanted (Fluad, Novartis)**

Pharmacology: Inactivated influenza vaccine.

Indication: Active immunization against influenza disease caused by influenza virus subtypes A and type B. Approved for use in patients  $\geq 65$  years.

Adverse Drug Reactions: Injection site pain, tenderness, myalgia, headache, and fatigue.

Dose: 0.5 mL dose for intramuscular injection.

Formulation: Suspension, 0.5 mL single-dose, pre-filled syringes.

Warnings/Contraindications: Syringe tips contain natural rubber latex which may cause allergic reactions in latex sensitive patients. Do not administer in patients with a severe allergic reaction to egg protein.

Notes: No studies have been conducted to evaluate potential drug-drug interactions with other vaccines.

**NUCALA (Mepolizumab, Glaxo SmithKline)**

Pharmacology: Interleukin-5 antagonist monoclonal antibody.

Indication: Add-on maintenance treatment of patients with severe asthma aged  $\geq 12$  years with an eosinophilic phenotype.

Adverse Drug Reactions: Headache, injection site reaction, back pain, and fatigue.

Dose: 100 mg subqQ injection administered once every 4 weeks.

Formulation: 100-mg lyophilized powder in a single-dose vial.

Warnings/Contraindications: Hypersensitivity reaction, herpes zoster infection.

Notes: Treat patients with pre-existing helminth infections before therapy. Do not use for patients with other eosinophilic conditions. Not for use for relief of acute bronchospasm or status asthmaticus.

**Elotizumab (Empliciti, Bristol Myers Squibb)**

Pharmacology: SLAMF7-directed immunostimulatory antibody.

Indication: Treatment of multiple myeloma in patients with lenalidomide and dexamethasone in patients who have received one to three prior therapies.

Adverse Drug Reactions: Fatigue, diarrhea, pyrexia, constipation, cough, peripheral neuropathy, nasopharyngitis, upper respiratory tract infection, decreased appetite, and pneumonia.

Dose: With lenalidomide and dexamethasone: 10 mg/kg IV every week for the first two cycles and every 2 weeks thereafter until disease progression or unacceptable toxicity.

Formulation: 300 mg or 400 mg lyophilized powder in a single-dose vial for reconstitution.

Warnings/Contraindications: Infusion reactions, infections, and hepatotoxicity.

Notes: Discontinue drug if elevations in liver enzymes greater than 3 X upper limit of normal.

**Daratumumab (Darzalex, Janssen Biotech)**

Pharmacology: Human CD-38 directed monoclonal antibody.

Indication: Treatment of patients with multiple myeloma who have received at least three prior lines of therapy including protease inhibitors (PI), an immunomodulatory agent, or who are double refractory to a PI and immunomodulatory agent.

Adverse Drug Reactions: Infusion reactions, fatigue, nausea, back pain, pyrexia, cough, upper respiratory tract infection.

Dose: 16 mg/kg intramuscular injection administered weekly for weeks 1-8, every 2 weeks (weeks 9-24) and every 4 weeks for week 25 and longer until disease progression.

Formulation: 100 mg/5 mL and 400 mg/20 mL in a single-dose vial.

Warnings/Contraindications: Infusion reactions.

Notes: May interfere with serological tests.

## NEW DRUG FORMULATIONS

**Halobetasol propionate (Ultravate, Ferndale Labs)**

Pharmacology: Topical corticosteroid.

Indication: Plaque psoriasis in patients > 18 years.

Dosage form: Topical lotion.

Dose: Apply thin layer twice weekly. Do not use > 50 g per week.

**Naloxone hydrochloride (Narcan, Adapt)**

Pharmacology: Opioid antagonist.

Indication: Emergency treatment of known or suspected opioid overdose, as evidenced by central nervous system or respiratory depression.

Dosage form: Nasal spray, 4 mg naloxone in 1 mL solution.

Dose: Take 1 spray in the nostril every 2-3 minutes until help arrives.

## NEW DRUG INDICATIONS

**Meloxicam (Vivlodex, Iroko Pharmaceuticals, LLC)**

Pharmacology: Non-steroidal anti-inflammatory drug (NSAID).

New Indication: For the treatment of osteoarthritis pain.

Dose: Starting dose is 5 mg once daily and can be increased to 10 mg once daily if needed for additional pain management.

**Anthrax Vaccine Adsorbed (BioThrax, Emergent BioSolutions)**

Pharmacology: Vaccine.

New Indication: Pre-exposure prophylaxis in patients at high risk of *Bacillus anthracis* and post-exposure prophylaxis following confirmed or suspected *Bacillus anthracis* exposure when used in conjunction with other antibacterial drugs.

Dose: Each dose is 0.5 mL.

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