



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](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Ibalizumab Uiyk (Trogarzo, Taimed Biologics USA)**

**Pharmacology:** CD-4 directed post attachment HIV-1 inhibitor.

**Indication:** Used in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current regimen.

**Adverse Drug Reactions:** Diarrhea, dizziness, nausea and rash.

**Dose:** 2,000 loading dose, followed by a maintenance dose of 800 mg every 2 weeks.

**Formulation:** Injection- 200 mg/1.33 mL in a single-dose vial.

**Warnings/Contraindications:** Immune reconstitution inflammatory syndrome.

**Notes:** Vials should be stored under refrigeration.

### **Tildrakizumab-Asmn (Ilumya, Merck Sharp Dohme)**

**Pharmacology:** Interleukin-23 antagonist.

**Indication:** Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

**Adverse Drug Reactions:** Upper respiratory infections, injection site reactions, and diarrhea.

**Dose:** 100 mg at weeks 0, 4, and every 12 weeks thereafter.

**Formulation:** Injection-100 mg/mL solution in a prefilled syringe.

**Warnings/Contraindications:** Hypersensitivity reactions, infections, and tuberculosis.

**Notes:** Avoid live vaccines in patients treated with tildrakizumab.

## NEW DRUG FORMULATIONS

### **Efavirenz; lamivudine; tenofovir disoproxil fumarate (Symfi, Matrix Labs)**

**Pharmacology:** Non-nucleoside reverse transcriptase inhibitor and nucleo(t)side reverse transcriptase inhibitors.

**Indication:** Treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg.

**Dosage form:** Tablets: 600 mg efavirenz, 300 mg lamivudine, and 300 mg tenofovir disoproxil fumarate.

**Dose:** One tablet once daily, taken on an empty stomach.

## NEW DRUG INDICATIONS

### **Blinatumomab (Blincyto, Amgen)**

**Pharmacology:** Bispecific CD19-directed CD3 T-cell engager.

**New Indication:** Minimal residual disease-positive B-cell precursor acute lymphoblastic leukemia.

**Dose:** Variable.

### **Insulin glargine [rDNA origin] Injection (Toujeo SoloStar, Sanofi)**

**Pharmacology:** Insulin.

**New Indication:** Long-acting human insulin analog.

**Dose:** Individualized.

**Nilotinib (Tasigna, Novartis)**

Pharmacology: Kinase inhibitor.

New Indication: Chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML).

Dose: 230 mg/m<sup>2</sup> twice daily, rounded to nearest 50 mg dose.

**Brentuximab Injection (Adcetris, Seattle Genetics, Inc.)**

Pharmacology: CD30-directed antibody-drug conjugate.

New Indication: First-line treatment of stage III or IV classical Hodgkin lymphoma in combination with chemotherapy.

Dose: 1.2 mg/kg as an intravenous infusion up to a maximum of 120 mg every 2 weeks for 12 doses.

**Ranibizumab (Lucentis, Genetech)**

Pharmacology: Humanized anti-VEGF antibody fragment.

New Indication: Diabetic macular edema and diabetic retinopathy.

Dose: 0.3 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days).

**Immune globulin subcutaneous (human) (Hizentra, CSL Behring)**

Pharmacology: Immune globulin.

New Indication: Chronic inflammatory demyelinating polyneuropathy.

Dose: 0.2 g/kg subcutaneously once weekly given in 1-2 sessions over 1-2 consecutive days beginning 1 week after the last IVIG infusion.

**Nivolumab (Opdivo, Bristol-Myers Squibb)**

Pharmacology: Programmed death receptor-1 (PD-1).

New Indication: Various cancers.

Dose: 480 mg infused every 4 weeks.

**Lurasidone (Latuda, Sunovion Pharmaceuticals)**

Pharmacology: Atypical antipsychotic.

New Indication: Bipolar depression in pediatric patients (10-17 years).

Dose: 20 – 80 mg per day.

**Ciprofloxacin (Otiprio, Otonomy, Inc)**

Pharmacology: Otic fluoroquinolone.

New Indication: Acute otitis externa.

Dose: Administer ciprofloxacin as a single 0.2 mL (12 mg) administration to the affected ear(s).

Prepared by: Maisha Kelly Freeman, PharmD, MS, BCPS, FASCP