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

**Prabotulinumtoxina-XVFS (Jeuveau, Evolus, Inc.)**
Pharmacology: Acetylcholine release inhibitor and neuromuscular blocking agent.
Indication: Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
Adverse Drug Reactions: Headache, eyelid ptosis, upper respiratory tract infection, and increase in white blood cell count.
Dose: Glabellar line administration-0.1 mL (4 units) by intramuscular injection into each of 5 sites (total dose 20 Units).
Formulation: 100 unit vacuum-dried powder.
Warnings/Contraindications: Cardiovascular adverse effects; concomitant neuromuscular disorder may exacerbate clinical effects of treatment; use caution in patients with compromised respiratory function or dysphagia.
Notes: Potency units of Jeuveau are not interchangeable with other preparations of botulinum toxin products.

**Caplacizumab-YHDP (Cablivi, Ablynx NV)**
Pharmacology: von Willebrand factor (vWF)-directed antibody fragment.
Indication: Treatment of adult patients with acquired thrombotic thrombocytopenic pupura (aTTP), in combination with plasma exchange and immunosuppressive therapy.
Adverse Drug Reactions: Epistaxis, headache, and gingival bleeding.
Dose: Varies; first day of treatment-11 mg bolus intravenous injection at least 15 minutes prior to plasma exchange followed by 11 mg subcutaneous injection after completion of plasma exchange on day 1.
Formulation: 11 mg as lyophilized powder.
Warnings/Contraindications: Bleeding.
Notes: Concomitant use of anticoagulants with caplacizumab-yhdp may increase the risk of bleeding.

**Triclabendazole (Egaten, Novartis Pharms Corp.)**
Pharmacology: Anthelmintic.
Indication: Treatment of fascioliasis in patients 6 years of age or older.
Adverse Drug Reactions: Abdominal pain, hyperhidrosis, nausea, decreased appetite, headache, urticarial, diarrhea, vomiting, musculoskeletal chest pain, and pruritus.
Dose: 2 doses of 10 mg/kg given every 12 hours apart in patients 6 years of age or older.
Formulation: Tablets, 250 mg.
Warnings/Contraindications: May prolong QT interval.
Notes: Swallow tablets whole or divide in half and take with water, crust and administer with applesauce.

**Trastuzumab; hyaluronidase-OYSK (Herceptin Hylecta, Genetech, Inc.)**
Pharmacology: HER2/neu receptor antagonist/ endoglycosidase.
Indication: Treatment of HER2-overepressing breast cancer.
Adverse Drug Reactions: Fatigue, arthralgia, diarrhea, injection site reaction, upper respiratory tract infection, rash, myalgia, nausea, headache, edema, flushing, pyrexia, cough, and pain in extremity.
Dose: 600 mg/10,000 units administered subcutaneously over approximately 2-5 minutes once every 3 weeks.
Formulation: Injection-600 mg trastuzumab and 10,000 units hyaluronidase per 5 mL.
Warnings/Contraindications: Exacerbation of chemotherapy-induced neutropenia; hypersensitivity and administration-related reactions.
Notes: Do not substitute Herceptin hylecta for or with ado-trastuzumab emtansine.

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## NEW DRUG FORMULATIONS

**Vancomycin (Vancomycin, Xellia Pharms APS)**
Pharmacology: Glycopeptide antibacterial.
Indication: Treatment of septicemia; infective endocarditis; skin and skin structure infections; bone infections and lower respiratory tract infections.
Dosage form: Single-dose flexible bags containing 500 mg vancomycin in 100 mL, 1 g vancomycin in 200 mL, 1.5 g vancomycin in 300 mL and 2 g vancomycin in 400 mL of liquid.
Dose: Varies; patients 1 month and older-10 mg/kg per dose given every 6 hours.; adult patients 2 g divided either as 0.5 g every 6 hours or 1 g every 12 hours.

**Loteprednol Etabonate (Lotemax SM, Bausch and Lomb, Inc.)**
Pharmacology: Corticosteroid.
Indication: Post operative inflammation and pain following ocular surgery.
Dosage form: Sterile preserved ophthalmic gel containing 3.8 mg per gram of gel.
Dose: One drop of loteprednol into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

**Methylphenidate hydrochloride (Adhansia XR, Purdue Pharma LP)**
Pharmacology: CNS stimulant.
Indication: Attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.
Dosage form: Extended-release capsules: 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, and 85 mg.
Dose: 25 mg once daily in the morning.

## NEW DRUG INDICATIONS

**Daratumumab (Darzalex, Janssen Biotech, Inc.)**
Pharmacology: Human anti-CD38 monoclonal antibody.
New Indication: Multiple myeloma.
Dose: 16 mg/kg, administered as a split-dosing regimen.

**Pembrolizumab (Keytruda, Merck)**
Pharmacology: Human PD-1 blocking antibody.
New Indication: Adjuvant treatment of melanoma with involvement of lymph nodes following complete resection.
Dose: 200 mg every 3 weeks.

**Tipiracil hydrochloride and trifluridine (Lonsurf, Taiho Oncology)**
Pharmacology: Thymidine phosphorylase inhibitor and nucleoside metabolic inhibitor.
New Indication: Treatment of patients with previously treated metastatic colorectal cancer and previously treated metastatic gastric or gastroesophageal junction adenocarcinoma.
Dose: 35 mg/m$^2$/dose orally twice daily with food on days 1 through 5 and days 8-12 of each 28-day cycle.

**Aprepitant (Cinvanti, Heron Therapeutics)**
Pharmacology: Substance P/neurokinin-1 (NK1) receptor antagonist.
New Indication: Prevention of chemotherapy-induced nausea and vomiting.
Dose: Administer intravenously as an injection over 2 minutes or an infusion over 30 minutes.

**Insulin glargine and lixisenatide (Soliqua, Sanofi)**
Pharmacology: Long acting human insulin and glucagon-like peptide-1 receptor agonist.
New Indication: Treatment of type 2 diabetes patients uncontrolled on oral antidiabetic medications.
Dose: Starting dose is 30 units subcutaneously once daily.

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