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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](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Pegfilgrastim-JMDB (Fulphila, Mylan GMBH)**

**Pharmacology:** Leukocyte growth factor.

**Indication:** Decrease infections in patients with with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with febrile neutropenia.

**Adverse Drug Reactions:** Bone pain and pain in extremity.

**Dose:** 6 mg administered subcutaneously once per chemotherapy cycle.

**Formulation:** Injection; solution containing 6 mg/0.6 mL solution.

**Warnings/Contraindications:** Fatal splenic rupture; acute respiratory distress syndrome; serious allergic reaction; fatal sickle cell crises; and glomerulonephritis.

**Notes:** Pegfilgrastim should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

### **Moxidectin (Moxidectin, Medicines Development for Global Health)**

**Pharmacology:** Anthelmintic.

**Indication:** Treatment of onchocerciasis due to *Onchocerca volvulus* in patients  $\geq 12$  years.

**Adverse Drug Reactions:** Eosinophilia, pruritus, musculoskeletal pain, headache, lymphopenia, tachycardia, rash, abdominal pain, hypotension, pyrexia, leukocytosis, influenza-like illness, neutropenia, cough, lymph node pain, dizziness, diarrhea, hyponatremia, and peripheral swelling.

**Dose:** Take 8 mg (four 2 mg tablets) as a single oral dose, with or without food.

**Formulation:** Tablets, 2 mg.

**Warnings/Contraindications:** Symptomatic orthostatic hypotension, encephalopathy, edema and worsening of onchodermatitis.

**Notes:** This agent does not kill adult *O. volvulus* parasites.

### **Plazomicin (Zemdri, Achaogen, Inc.)**

**Pharmacology:** Aminoglycoside antibacterial.

**Indication:** Treatment of complicated urinary tract infections, including pyelonephritis, in adult patients.

**Adverse Drug Reactions:** Decreased renal function, diarrhea, hypertension, headache, nausea, vomiting, and hypotension.

**Dose:** 15 mg/kg every 24 hours by intravenous infusion over 30 minutes with a creatinine clearance  $\geq 90$  mL/min.

**Formulation:** 500 mg/10 mL in a single-dose vial.

**Warnings/Contraindications:** Hypersensitivity reactions; *Clostridium difficile*-associated diarrhea.

**Notes:** Dosage adjustments are necessary in patients with a creatinine clearance  $\leq 60$  mL/min.

### **Cannabidiol (Epidiolex, GW Research, LTD)**

**Pharmacology:** Cannabinoid.

**Indication:** Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age or older.

**Adverse Drug Reactions:** Somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue; malaise; asthenia; rash; insomnia; sleep disorder; poor quality sleep; and infections.

**Dose:** 2.5 mg/kg twice daily. After one week, the dosage can be increased to 5 mg/kg twice daily. The maximum recommended maintenance dosage is 10 mg/kg twice daily.

**Formulation:** Oral solution: 100 mg/mL.

**Warnings/Contraindications:** Hepatocellular injury; somnolence and sedation; suicidal behavior and ideation; hypersensitivity reactions; withdrawal of antiepileptic drugs.

**Notes:** Dosage reduction of the cannabinoid may be needed when used concomitantly with moderate or strong inhibitors of CYP3A4 or CYP2C19.

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**Binimetinib (Mektovi, Array Biopharma, Inc)**

Pharmacology: Kinase inhibitor.

Indication: In combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.

Adverse Drug Reactions: Fatigue, nausea, diarrhea, vomiting, and abdominal pain.

Dose: 45 mg orally twice daily in combination with encorafenib.

Formulation: Tablets: 15 mg.

Warnings/Contraindications: Cardiomyopathy, venous thromboembolism, ocular toxicities, interstitial lung disease, hepatotoxicity, rhabdomyolysis, hemorrhage, and embryo-fetal toxicity.

Notes: Patients with moderate or severe hepatic impairment should receive 30 mg twice daily.

## NEW DRUG FORMULATIONS

**Doxycycline Hyclate (Lymepak, Chartwell Pharma)**

Pharmacology: Tetracycline.

Indication: Treatment of early Lyme disease due to *Borrelia burgdorferi* in adults and pediatric patients 8 years of age and older weighing 45 kg and above.

Dosage form: Tablets containing 100 mg doxycycline.

Dose: 100 mg every 12 hours for 21 days.

**Desmopressin Acetate (Nocurna, Ferring Pharms Inc)**

Pharmacology: Vasopressin analog.

Indication: Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Dosage form: Sublingual tablets-27.2 mcg of desmopressin acetate and 55.3 mcg of desmopressin acetate.

Dose: Women: 27.7 mcg daily, one hour before bedtime; women 55.3 mcg daily, one hour before bedtime.

**Dehydrated alcohol (Ablysinol, Belcher Pharms, LLC)**

Pharmacology: Ablative agent.

Indication: Induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy.

Dosage form: Injection: 1 mL or 5 mL of ethyl alcohol.

Dose: Inject small volumes over 1-2 minutes percutaneously into septal arterial branches. In most cases, 1-2 mL is appropriate. The maximum dose used in a single procedure is 5 mL.

**Glycopyrronium (Qbrexza, Dermira, Inc)**

Pharmacology: Anticholinergic.

Indication: Topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Dosage form: Single use cloth pre-moistened with 2.4 glycopyrronium solution.

Dose: Apply once daily to both axillae using a single cloth.

**Aripiprazole Lauroxil (Aristada Initio, Alkermes)**

Pharmacology: Atypical antipsychotic.

Indication: Treatment of schizophrenia in adults.

Dosage form: Extended-release injectable suspension (675 mg single-dose pre-filled syringe).

Dose: One 675 mg injection and one 30 mg dose of oral aripiprazole.

## NEW INDICATIONS

**Bevacizumab (Avastin, Genetech)**

Pharmacology: Recombinant humanized monoclonal IgG1 antibody.

New Indication: Treatment for women with advanced ovarian cancer following initial surgery in combination with chemotherapy.

Dose: 15 mg/kg.

**Pembrolizumab (Keytruda, Merck)**

Pharmacology: Human PD-1 (programmed death receptor -1)- blocking agent.

New Indication: Treatment of refractory or relapsed primary mediastinal large B-cell lymphoma.

Dose: 200 mg.

**Venetoclax (Venclexta, Genetech)**

Pharmacology: Oral B-cell lymphoma-2 (BCL-2) inhibitor.

New Indication: In combination for people with previously treated chronic lymphocytic leukemia.

Dose: Initiate therapy at 20 mg once daily for 7 days, followed by a weekly ramp-up dosing schedule to a recommended daily dose of 400 mg.

**Rituximab (Rituxan, Genetech)**

Pharmacology: CD20-directed cytolytic antibody.

New Indication: Treatment of pemphigus vulgaris.

Dose: Two, 1000-mg intravenous infusions separated by 2 weeks in combination with a tapering course of glucocorticoids, then a 500 mg intravenous infusion at month 12 and every 6 months thereafter.