

# 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](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Sarecycline hydrochloride (Seysara, Allergan, Inc)**

**Pharmacology:** Tetracycline antibacterial.

**Indication:** Treatment of inflammatory lesions of the non-nodular moderate to severe acne vulgaris in patients 9 years and older.

**Adverse Drug Reactions:** Nausea.

**Dose:** 60 mg for patients who weigh 33-54 kg; 100 mg for patients who weigh 55-84 kg; 150 mg for patients who weigh 85-136 kg.

**Formulation:** Tablets-60 mg, 100 mg, 150 mg.

**Notes:** Avoid coadministration with oral retinoids.

### **Omadacycline Tosylate (Nuzyra, Paratek Pharms, Inc)**

**Pharmacology:** Tetracycline antibacterial.

**Indication:** Community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

**Adverse Drug Reactions:** Nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

**Dose:** Varies by indication.

**Formulation:** 100 mg of omadacycline (equivalent to 131 mg omadacycline tosylate) as a lyophilized powder.

**Notes:** Patients who are receiving anticoagulant therapy may require a downward adjustment of their anticoagulant dose.

### **Inotersen Sodium (Tegsedi, Akcea Theraps)**

**Pharmacology:** Transthyretin-directed antisense oligonucleotide.

**Indication:** Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

**Adverse Drug Reactions:** Injection site reactions, nausea, headache, fatigue, thrombocytopenia, and fever.

**Dose:** 284 mg administered by subcutaneous injection once weekly.

**Formulation:** 284/1.5 mL in a single-dose prefilled syringe.

**Notes:** Contraindicated in patients with platelet counts less than  $100 \times 10^9/L$  and acute glomerulonephritis.

### **Elapegademase-LVLR (Revcovi, Leadiant Biosci, Inc.)**

**Pharmacology:** Recombinant adenosine deaminase.

**Indication:** Treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

**Adverse Drug Reactions:** Cough and vomiting.

**Dose:** Varies based on indication. Should only be administered intramuscularly.

**Formulation:** Injection: 2.4 mg/1.5 mL (1.6 mg/mL) in a single-dose vial.

**Notes:** May delay in improvement of immune function.

### **Talazoparib Tosylate (Talzenna, Pfizer, Inc)**

**Pharmacology:** Poly (ADP-ribose) polymerase (PARP) inhibitor.

**Indication:** Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.

**Adverse Drug Reactions:** Fatigue, anemia, nausea, neutropenia, headache, thrombocytopenia, vomiting, alopecia, diarrhea, decreased appetite.

**Dose:** The recommended dose is 1 mg as a single oral daily dose with or without food.

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**Talazoparib Tosylate (Talzenna, Pfizer, Inc) (continued)**

Formulation: Capsules, 0.25 mg and 1 mg.

Notes: The talazoparib dose should be decreased in patients receiving P-gp inhibitors. Patients should be monitored for increased adverse reactions when taking concomitant BCRP inhibitors.

**Levoleucovorin (Khapzory, Spectrum Pharms)**

Pharmacology: Folate analog.

Indication: Rescue after high dose methotrexate therapy in patients with osteosarcoma; diminish toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination; treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

Adverse Drug Reactions: Stomatitis and vomiting.

Dose: Varies based on indication.

Formulation: Injection: 175 and 300 mg of levoleucovorin lyophilized powder in a single-dose vial for reconstitution.

Notes: Levoleucovorin is not indicated for treatment of pernicious anemia and megaloblastic anemia. Do not administer intrathecally.

**Baloxavir Marboxil (Xofluza, Genetech, Inc.)**

Pharmacology: Polymerase acidic (PA) endonuclease inhibitor.

Indication: Treatment of acute uncomplicated influenza in patients 12 years of age and older who have not displayed symptoms for more than 48 hours.

Adverse Drug Reactions: Diarrhea, bronchitis, nasopharyngitis, headache, and nausea.

Dose: The dose is based on weight. Patients who are 40 kg to < 80 kg should receive a single baloxavir dose of 40 mg. Patients at least 80 kg should receive a single baloxavir dose of 80 mg.

Formulation: Tablets 20 and 40 mg.

Notes: Avoid coadministration with polyvalent cation-containing laxatives, antacids, or oral supplements.

**Adalimumab-Adaz (Hyrimoz, Sandoz, Inc.)**

Pharmacology: Tumor necrosis factor; Biosimilar to Humira.

Indication: Indicated for several conditions including rheumatoid arthritis; juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; adult Crohn's disease; ulcerative colitis; and plaque psoriasis.

Adverse Drug Reactions: Infections, injection site reactions, headache, and rash.

Dose: Varies based on indication.

Formulation: Injection: 40 mg/0.8mL vial or 40 mg/0.8mL single-dose pen.

Notes: There are increased risks of drug interactions if coadministered with the following agents: abatacept, anakinra, and live vaccines.

## **NEW DRUG FORMULATIONS**

**Meloxicam (Qmiz ODT, Tersera Theraps, LLC)**

Pharmacology: Non-steroidal anti-inflammatory drug.

Indication: Rheumatoid or Osteoarthritis in adults and Juvenile Rheumatoid Arthritis in children.

Dosage form: Orally disintegrating tablet: 7.5 mg and 15 mg.

Dose: The starting dose is 7.5 mg once daily and can be increased to 15 mg.

**Estradiol; Progesterone (Bijuva, TherapeuticsMD, Inc)**

Pharmacology: Combination of estrogen and progesterone.

Indication: Treatment of moderate-to-severe vasomotor symptoms in menopausal women with an intact uterus.

Dosage form: 1 mg estradiol/100 mg progesterone.

Dose: Take 1 capsule orally each evening with food.

**Calcium Gluconate in Sodium Chloride (Calcium Gluconate, HQ SPCLT )**

Pharmacology: Electrolytes.

Indication: Treatment of acute symptomatic hypocalcemia.

Dosage form: Intravenous.

Dose: Varies based on calcium level.