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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

Prucalopride (Motegrity, Shire Dev LLC)

Pharmacology: Serotonin-4 (5-HT₄) receptor agonist.

Indication: Treatment of chronic idiopathic constipation in adults.

Adverse Drug Reactions: Headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue.

Dose: Adults-2 mg once daily.

Formulation: Tablets containing 1 mg and 2 mg of prucalopride.

Warnings/Contraindications: Intestinal perforation or obstruction.

Notes: Patients with a renal insufficiency (CrCL <30 mL/min) should receive 1 mg once daily.

Trastuzumab-PKRB (Herzuma, Celltrion, Inc.)

Pharmacology: HER₂/neu receptor antagonist.

Indication: Treatment of HER₂-overexpressing breast cancer.

Adverse Drug Reactions: Headache, diarrhea, nausea, and chills.

Dose: Initial dose is 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose, 6 mg/kg as an IV infusion should be administered over 30-90 minutes every 3 weeks to complete 52 weeks of therapy.

Formulation: 420 mg lyophilized powder.

Warnings/Contraindications: Exacerbation of chemotherapy-induced neutropenia.

Notes: Trastuzumab-pkrb should not be substituted for or with ado-trastuzumab emtansine.

Calaspargase Pegol-MKNL (Asparlas, Servier Pharma, LLC)

Pharmacology: Asparagine-specific enzyme.

Indication: Treatment of acute lymphoblastic leukemia in patients aged 1 month to 21 years as a combination therapy.

Adverse Drug Reactions: Elevated transaminase, bilirubin increased, pancreatitis, and abnormal clotting.

Dose: 2,500 units/m² intravenously no more than 21 days.

Formulation: Injection-3,750 units/5mL (750 units/mL) in a single-dose vial.

Warnings/Contraindications: Hypersensitivity, pancreatitis, thrombosis, hemorrhage, or hepatotoxicity.

Notes: Women should not breastfeed while using Calaspargase Pegol-MKNL.

Ravulizumab-CWVZ (Ultomiris, Alexion Pharm.)

Pharmacology: Complement inhibitor.

Indication: Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

Adverse Drug Reactions: Upper respiratory infection and headache.

Dose: Weight-based dosing from 2,400 mg loading dose to a 3,600 mg maintenance dose.

Formulation: Injection: 300 mg/30 mL (10 mg/mL) in a single-dose vial.

Warnings/Contraindications: Unresolved *Neisseria Meningitidis* infection or other systemic infection.

Notes: Ravulizumab-CWVZ is only available through a restricted program under REMS.

NEW DRUG APPROVALS (CONTINUED)

Tagraxofusp-ERZS (Elzonris, Stemline Therapeutics, Inc.)

Pharmacology: CD123-directed cytotoxin.

Indication: Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older.

Adverse Drug Reactions: Capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase.

Dose: 12 mcg/kg over 15 minutes once daily on days 1 to 5 of a 21-day cycle.

Formulation: Injection-1000 mcg in a 1mL single-dose vial.

Warnings/Contraindications: Hypersensitivity and hepatotoxicity.

Notes: Monitor ALT/AST. Discontinue therapy if transaminases rise to greater than 5 times the upper limit of normal.

NEW DRUG FORMULATIONS

Itraconazole (Tolsura, Mayne Pharma Inc.)

Pharmacology: Azole antifungal.

Indication: Blastomycosis, pulmonary and extra pulmonary; histoplasmosis; and aspergillosis in patients who are intolerant of or who are refractory to amphotericin B therapy.

Dosage form: 65-mg capsules.

Dose: Varies, depending on indication from 130 to 260 mg daily.

Rosuvastatin (Ezallor, Sun Pharma Global)

Pharmacology: HMG Co-A reductase inhibitor.

Indication: Adult patients with hypertriglyceridemia; primary dysbetalipoproteinemia; and homozygous familial hypercholesterolemia.

Dosage form: Capsules (5 mg, 10 mg, 20 mg, and 40 mg).

Dose: Varies, dosage range is from 5 to 40 mg once daily.

Diclofenac Epolamine (Licart, Institut Biochimique)

Pharmacology: Topical NSAID.

Indication: Topical treatment of acute pain due to minor strains, sprains, and contusions.

Dosage form: Topical system 1.3%.

Dose: Administer once daily.

Levetiracetam (Elepsia XR, Sun Pharma Global)

Pharmacology: Antiepileptic.

Indication: Adjunctive treatment for partial onset seizures.

Dosage form: Extended-release tablets, 1000 mg, 1500 mg.

Dose: Initiate treatment with a dose 1000 mg once daily; increase by 1000 mg every 2 weeks to a maximum recommended dose of 3000 mg once daily.

Levodopa (Inbrija, Accordia)

Pharmacology: Aromatic amino acid.

Indication: Intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

Dosage form: Inhalation powder in capsule form containing 42 mg levodopa.

Dose: Two capsules (84 mg) as needed for OFF symptoms, up to 5 times daily. The maximum recommended daily dose of inhaled levodopa is 420 mg.

NEW INDICATIONS

Atezolizumab (Tecentriq, Genetech)

Pharmacology: Anti-PD-L1 monoclonal antibody.

New Indication: Combination therapy for metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.

Dose: 1,200 mg on day 1 every 3 weeks for 4-6 cycles; followed by 1,200 mg on day 1 every 3 weeks until disease progression or unacceptable toxicity.

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NEW INDICATIONS (CONTINUED)

Romiplostim (Nplate, Amgen)

Pharmacology: Colony stimulating factor.

New Indication: Treatment of immune thrombocytopenia (ITP) for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy in pediatric patients aged 1 year of age or older.

Dose: 1 mcg/kg once weekly as a subcutaneous injection.

Tacrolimus Extended-release (Envarsus XR, Veloxis Pharmaceuticals)

Pharmacology: Immunosuppressant agent.

New Indication: Prevent organ rejection in de novo kidney transplant patients in combination with other immunosuppressants.

Dose: 0.14 mg/kg/day; titrate to target trough concentrations.

Olaparib (Lynparza, AstraZeneca/Merck)

Pharmacology: Antineoplastic agent.

New Indication: Maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.

Dose: 300 mg (tablets) twice daily.

Pembrolizumab (Keytruda, Merck)

Pharmacology: Anti-PD-1 monoclonal antibody.

New Indication: Recurrent locally advanced or metastatic merkel cell carcinoma.

Dose: 200 mg IV once every 3 weeks until disease progression, unacceptable toxicity for up to 24 months.

Glycerol phenylbutyrate (Raviciti, Horizon Pharma)

Pharmacology: Nitrogen-binding agent.

New Indication: Treatment of urea cycle disorder (UCD) in adults and children of all ages who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

Dose: 4.5 to 11.2 mL/m²/day.