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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

Romosozumab-AQQG (Evenity, Amgen, Inc.)

Pharmacology: Sclerostin inhibitor.

Indication: Treatment of osteoporosis in postmenopausal women with a high fracture risk.

Adverse Drug Reactions: Arthralgia and headache.

Dose: 210 mg subcutaneously once every month for 12 doses in the abdomen, thigh, or upper arm.

Formulation: Injection: 105 mg/1.17 mL solution in a single-use, prefilled syringe.

Warnings/Contraindications: Major adverse cardiac events; hypersensitivity; hypocalcemia; osteonecrosis of the jaw; and atypical femoral fracture.

Notes: Patients with severe renal impairment or those receiving dialysis are at a greater risk of hypocalcemia. Monitor serum calcium and supplement with calcium and vitamin D.

Erdafitinib (Balversa, Janssen Biotech)

Pharmacology: Kinase inhibitor.

Indication: Treatment of adult patients with locally advanced or metastatic urothelial carcinoma.

Adverse Drug Reactions: Phosphate increased, stomatitis, fatigue, creatinine increased, diarrhea, dry mouth, onycholysis, alanine aminotransferase increased, alkaline phosphatase increased, sodium decreased, decreased appetite, albumin decreased, dysgeusia, hemoglobin decreased, dry skin, aspartate aminotransferase increased, magnesium decreased, dry eye, alopecia, palmar plantar erythrodysesthesia syndrome, constipation, phosphate decreased, abdominal pain, calcium increased, nausea, and musculoskeletal pain.

Dose: The initial dose is 8 mg orally once daily with a dose increase to 9 mg daily if criteria are met.

Formulation: Tablets, 3 mg, 4 mg, and 5 mg.

Warnings/Contraindications: Ocular disorders; hyperphosphatemia; and embryo-fetal toxicity.

Notes: Consider alternative agents for medications that are strong CYP2C9 or CYP3A4 inhibitors; strong CYP2C9 or CYP3A4 inducers; CYP3A4 substrates; OCT2 substrates; or P-gp substrates. Avoid concomitant use with serum phosphate level-altering agents.

Risankizumab-RZAA (Skyriz, Abbvie, Inc.)

Pharmacology: Interleukin-23 antagonist.

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

Adverse Drug Reactions: Upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

Dose: 150 mg (two 75 mg injections) administered by subcutaneous injection at week 0, 4, and every 12 weeks thereafter.

Formulation: Injection-75 mg/0.83 mL in each single-dose prefilled syringe.

Warnings/Contraindications: May increase the risk of infections and tuberculosis.

Notes: Avoid use of live vaccines with risankizumab.

Etanercept-YKRO (Eticovo, Samsung Bioepis Co, LTD.)

Pharmacology: Tumor necrosis factor (TNF) blocker.

Indication: Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis; and plaque psoriasis.

Adverse Drug Reactions: Infections and injection site reactions.

Dose: Varies, based on indication.

Formulation: Injection 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe.

Etanercept-YKRO (Eticovo, Samsung Bioepis Co, LTD.) (continued)

Warnings/Contraindications: Active infection; demyelinating disease; lymphoma; congestive heart failure; anaphylaxis; lupus-like syndrome.

Notes: Avoid concomitant use with live vaccines, anakinra, abatacept, and cyclophosphamide.

NEW DRUG FORMULATIONS

Colesevelam Hydrochloride (Welchol, Daiichi Sankyo, Inc)

Pharmacology: Bile acid sequestrant.

Indication: Reduce elevated LDL, and improve glycemic control in adults with type 2 diabetes mellitus.

Dosage form: Chewable bars-3.75 gram per bar.

Dose: Take one bar once daily with a meal.

Dolutegravir; Lamivudine (Dolutegravir; Lamivudine, Viiv Hlthcare)

Pharmacology: Integrase strand transfer inhibitor [INSTI] and nucleoside analogue reverse transcriptase inhibitor [NRTI].

Indication: Treatment of HIV-1 infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components.

Dosage form: Tablets 50 mg dolutegravir and 300 mg lamivudine.

Dose: One tablet taken orally once daily with or without food.

Levothyroxine Sodium (Levothyroxine Sodium, Fresenius Kabi, USA)

Pharmacology: L-thyroxine (T4).

Indication: Treatment of myxedema coma.

Dosage form: Injection 100 mcg per 5 mL, 200 mcg per 5 mL, 500 mcg per 5 mL

Dose: Loading dose- 300-500 mcg administered intravenously.

Tranexamic Acid in Sodium Chloride Injection (Tranexamic Acid in Sodium Chloride Injection, Exela Pharma Science)

Pharmacology: Antifibrinolytic.

Indication: Patients with hemophilia for short-term use (2-8 days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

Dosage form: Injection-1000 mg of tranexamic acid in 100 mL.

Dose: Before extraction: 10 mg/kg actual body weight; after extraction 10 mg/kg actual body weight 3-4 times daily for 2-8 days.

Cysteine Hydrochloride (Elcys, Exela Pharma SCS, LLC)

Pharmacology: Sulfur-containing amino acid.

Indication: Meet the nutritional requirements of newborn infants requiring total parental nutrition and patients with severe liver disease.

Dosage form: Injection-500 mg/10 mL.

Dose: Dosing varies based on age and protein requirements.

Ivabradine (Corlanor, Amgen)

Pharmacology: Hyperpolarization-activated cyclic nucleotide-gated channel blocker.

Indication: Reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced LVEF. Treatment of stable symptomatic heart failure due to dilated cardiomyopathy.

Dosage form: Tablets: 5 mg, 7.5 mg; Oral solution: 5 mg/5mL

Dose: Varies based on age.

Halobetasol Propionate; Tazarotene (Duobrii, Bausch Health Americans, Inc.)

Pharmacology: Corticosteroid/retinoid combination drug.

Indication: Topical treatment of plaque psoriasis.

Dosage form: Lotion, 0.01%/0.045%.

Dose: Apply thin layer once daily.

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