CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
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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

Moxetumomab Pasudotox-TDFK (Lumoxiti, AstraZeneca)
Pharmacology: CD22-directed cytotoxin.
Indication: Treatment of adult patients with relapsed or refractory hairy cell leukemia who have received at least two prior systemic therapies.
Adverse Drug Reactions: Infusion-related reactions, edema, nausea, fatigue, headache, pyrexia, constipation, anemia and diarrhea. Other reactions include the following laboratory abnormalities: creatinine incrased, AST/ALT increased, hypoalbuminemia, hypocalcemia, and hypophosphatemia.
Dose: The dose is 0.04 mg/kg as an intravenous infusion over 30 minutes on Days 1, 3, and 5 of a 28-day cycle.
Warnings/Contraindications: Renal toxicity; infusion related reactions; electrolyte abnormalities.
Notes: Do not use in patients with severe renal impairment (CrCL ≤29 mL/min).

Fremanezumab-VFRM (Ajovy, Teva Pharms)
Pharmacology: Calcitonin gene-related peptide antagonist.
Indication: Preventative treatment of migraine headaches in adults.
Adverse Drug Reactions: Injection site reactions.
Dose: A dose of 225 mg monthy or 675 mg every 3 months is administered subcutaneously.
Warnings/Contraindications: Hypersensitivity reactions.
Notes: Administer in abdomen, thigh or upper arm.

Duvelisib (Copiktra, Verastem, Inc)
Pharmacology: Kinase inhibitor.
Indication: Treatment for relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lympohoma (SLL); relapsed or refractory follicular lymphoma (FL). Both therapies should be administered prior to systemic therapies.
Adverse Drug Reactions: Diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia.
Dose: The dose is 25 mg orally twice daily.
Warnings/Contraindications: Fatal and/or serious cases of the following: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis.
Notes: Avoid co-administration with strong CYP3A4 inducers. Dosage reductions of duvelisib may be needed with concomitant administration with CYP3A inhbitors and CYP3A substrates.

Dacomitinib (Vizimpro, Pfizer, Inc)
Pharmacology: Kinase inhibitor.
Indication: First-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations.
Adverse Drug Reactions: Diarrhea, rash, paronchia, stomatitis, decreased appetite, dry skin, decreased weight, alopecia, cough, and pruritus.
Dose: The dose is 45 mg orally once daily with or without food.
Warnings/Contraindications: Interstitial lung disease, diarrhea, dermatologic adverse reactions, and embryo-fetal toxicity.
Notes: Avoid use with proton pump inhibitors or CYP2D6 substrates.

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Galcanezumab-GNLM (Emgality, Eli Lilly and Co.,)
Pharmacology: Calcitonin-gene related peptide antagonist.
Indication: Prevention of migraine headaches in adults.
Adverse Drug Reactions: Injection site reactions.
Dose: A 240 mg loading dose (administered as two consecutive injections of 120 mg each) is recommended, followed by monthly doses of 120 mg administered in the abdomen, thigh, back of upper arm or buttocks.
Warnings/Contraindications: Hypersensitivity reactions.
Notes: No dosage changes are needed in patients with renal or hepatic impairment.

Cemiplimab (Libtayo, Regeneron Pharamceuticals)
Pharmacology: Programmed death receiptor-1 (PD-1) blocking antibody.
Indication: Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for surgery or radiation.
Adverse Drug Reactions: Fatigue, rash, and diarrhea.
Dose: The dose is 350 mg, as intravenous infusion, over 30 minutes every 3 weeks.
Warnings/Contraindications: Severe and fatal immune-mediated adverse reactions; infusion-related reactions; embryo-fetal toxicity.
Notes: Depending on the severity of adverse reactions, cemiplimab dosage reductions may be necessary.

NEW DRUG FORMULATIONS

Riluzole (Tiglutik, Italfarmaco SPA)
Pharmacology: Glutamate inhibitor.
Indication: Treatment of amotrophic lateral sclerosis.
Dosage form: Oral suspension.
Dose: The dose is 50 mg twice daily, taken orally, every 12 hours at least 1 hour before or 2 hours after meals.

Buprenorphine; Naloxone (Cassipa, Teva Pharmaceuticals)
Pharmacology: Parial-opioid agonist and opioid antagonist.
Indication: Maintenance treatment of opioid dependence.
Dosage form: Sublingual film.
Dose: The dose is 16 mg/4mg dose should only be used after induction and stabilization of the patient and when the patient has been titrated to a dose of 16 mg buprenorphine using another product.

Latanoprost (Xelpros, Sun Pharma Global)
Pharmacology: Prostaglandin F_{2alpha} analog.
Indication: Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
Dosage form: Ophthalmic emulsion (50 mcg/mL).
Dose: One drop in the affected eye once daily in the evening.

Amikacin (Arikayce, Insmed)
Pharmacology: Aminoglycoside antibacterial.
Indication: *Mycobacterium avium complex* (MAC) lung disease, as combination therapy.
Dosage form: Oral inhalation containing amikacin 590 mg/8.4 mL.
Dose: Oral inhalation of the contents of one vial containing amikacin 590 mg/8.4 mL).

Testosterone enanthate (Xyosted, Antares Pharma, Inc)
Pharmacology: Androgen.
Indication: Testosterone replacement therapy in adult males.
Dosage form: Injection supplied as 50 mg/0.5 mL; 75 mg/0.5 mL; 100 mg/0.5 mL.
Dose: The starting dose is 75 mg subcutaneously in the abdominal region once weekly.

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