CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
McWhorter School of Pharmacy

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

Fostamatinib (Tavalisse, Rigel Pharms, Inc.)
Pharmacology: Kinase inhibitor.
Indication: Treatment of thrombocytopenia in adult patients with chornic immune thrombocytopenia (ITP) who have had an insufficient response to previous treatment.
Adverse Drug Reactions: Diarrhea, hypertension, nausea, repiratory infection, dizziness, ALT/AST increased, rash, abdominal pain, fatigue, chest pain and neutropenia.
Dose: 100 mg twice daily with or without food. After 4 weeks, the dosage can be increased to 150 mg twice daily to achieve a platelet count at least 50 X 10^9/L.
Formulation: 100-mg, and 150-mg, tablets.
Warnings/Contraindications: Hypertension, hepatotoxicity, diarrhea, neutropenia, and embryo-fetal toxicity.
Notes: Concomitant use with strong CYP3A4 inhibotor increases expore to the active metabolite. Use is not recommended in combination with strong CYP3A4 inducers.

Burosumab-Twza (Crysvita, Ultragenyx Pharm, Inc.)
Pharmacology: Fibroblast growth factor 23 (FGF 23) blocking antibody.
Indication: Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients ≥ 1 year.
Adverse Drug Reactions: Headache, injection site reaction, vomiting, pyrexia, pain in extremity, and decrease in vitamin D.
Dose: Adults: 1 mg/kg body weight rounded to the nearest 10 mg, up to a maximum dose of 90 mg administered every 4 weeks. Pediatric dose is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, up to a maximum dose of 90 mg. Dose may be increased up to 2 mg/kg, administered every 2 weeks to achieve normal serum phosphorus.
Formulation: Injection: 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vial.
Warnings/Contraindications: Hypersensitivity, hyperphosphatemia and risk of nephrocalcinosis, and injection site reactions.
Notes: Do not use with oral phosphate and active vitamin D analogs. Do not use in patients with several renal impairment or end stage renal disease.

Fosneteupitant; palonosetron hydrocholoride (Akynzeo, Helsinn Healthcare)
Pharmacology: Selective antagonist of human substance P/neurokinin 1 (NK-1) receptor/ 5HT3 receptor antagonist.
Indication: Prevention of acute and delayed nausea and vomiting associated with chemotherapy treatment.
Adverse Drug Reactions: Headache, asthenia, dyspepsia, fatigue, constipation, and erythema.
Dose: One capsule approximately 1 hour prior to the start of chemotherapy, with or without food. One vial of the injection, reconstituted in 50 mL of 5% dextrose injection, administered as a 30-minute infusion starting 30 minutes prior to the start of chemotherapy.
Formulation: Capsules: 300 mg fosneteupitant / 0.5 mg palonestron; Injection: 235 mg fosnetupitant / 0.35 mg palonestron.
Warnings/Contraindications: Hypersensitivity reactions, serotonin syndrome.
Notes: Avoid use with CYP3A4 inducers; avoid concomitant CYP3A4 substrates for 1 week, or consider dose reduction of CYP3A4 substrate.

NEW DRUG FORMULATIONS

Hydrocodone bitartrate; guaifenesin (Hydrocodone bitartrate; guaifenesin, Eci Pharms, LLC.)
Pharmacology: Opioid agonist and expectorant.
Indication: Symptomatic relief of cough and to loosen mucus associated with the common cold.
Dosage form: Tablets containing hydrocodone bitartrate 5 mg and guaifenesin 400 mg.
Dose: Adults-one tablet every 4-6 hours (do not exceed 6 tablets in 24 hours).

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NEW DRUG INDICATIONS

Tolvaptan (Jynarque, Otsuka Pharm, Co. LTD)
Pharmacology: Selective vasopressin-receptor antagonist.
New Indication: Slow kidney function decline in patients at risk of rapidly progressing autosomal dominant polycystic kidney disease.
Dose: The initial dose is 45 mg.

Dabrafenib (Tafinlar, Novartis)
Pharmacology: Kinase inhibitor.
New Indication: Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation.
Dose: 150 mg twice daily.

Mirabegron (Myrbetriq, Astellas Pharma, Inc.)
Pharmacology: Beta-3 adrenergic agonist.
New Indication: Treatment of overactive bladder in combination with solifenacin succinate.
Dose: 50 mg orally once daily.

Osimertinib (Tagrisso, AstraZeneca)
Pharmacology: Tyrosine kinase inhibitor (TKI) of epidermal growth factor receptor (EGFR).
New Indication: First-line treatment of EGFR T790 Mutation-positive non-small cell lung cancer.
Dose: 80 mg orally once daily.

Nivolumab (Opdivo, Bristol-Myers Squibb)
Pharmacology: Programmed dealth receptor-1 (PD-1) blocking antibody.
New Indication: First-line treatment for patients with intermediate-and poor-risk advanced renal cell carcinoma.
Dose: 3 mg/kg administered intravenously.

Von willebrand factor (recombinant) for Injection (Vonvendi, Shire)
Pharmacology: Recombinant von Willebrand factor (VWF).
New Indication: Perioperative management of bleeding in adult patients with von Willebrand disease.
Dose: 40-60 IU per kg body weight 12 – 24 hours before surgery.

Idarucizumab (Praxbind, Boehringer Ingelheim)
Pharmacology: Humanized monoclonal antibody fragment (Fab).
New Indication: Reversal agent for dabigatran.
Dose: 5 g, administered as two separate vials containing 2.5 g/50 mL idarucizumab.

Everolimus (Afinitor, Novartis)
Pharmacology: mTOR inhibitor.
New Indication: Tuberous sclerosis complex-associated partial onset seizures.
Dose: 3-6 mg/m^2 depending on age.

Rucaparib (Rubraca, Clovis Oncology)
Pharmacology: Poly (ADP-ribose) polymerase (PARP) inhibitor.
New Indication: Maintenance treatment of recurrent ovarian cancer.
Dose: 600 mg twice daily.

Bupivacaine liposome (Exparel, Pacira)
Pharmacology: Long-acting non-opioid local analgesic.
New Indication: Nerve block to produce regional analgesia.
Dose: 133 mg in 20 mL total volume.

Exenatide extended-release injectable suspension (Bydureon, AstraZeneca)
Pharmacology: Glucagon-like peptide-1 (GLP-1) receptor agonist.
New Indication: Inadequate glycemic control in combination with basal insulin in patients with type 2 diabetes.
Dose: 2 mg by subcutaneous injection once weekly.

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