CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY SAMFORD UNIVERSITY
Preparing Pharmacists Who Transform Lives

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 (205) 726-2891.

NEW DRUG APPROVALS

Aripiprazole lauroxil (Aristada, Alkermes)
Pharmacology: Atypical Antipsychotic.
Indication: For the treatment of schizophrenia.
Adverse Drug Reactions: Most common adverse reaction is akathisia.
Dose: Patients may be initiated on 441 mg, 662 mg, or 882 mg administered monthly, or every 6 weeks for the 882 mg dose. The 441 mg may be administered by IM injection in the deltoid or gluteal muscle. Doses of 662 mg and 882 mg should be administered in the gluteal muscle only.
Formulation: 441-mg, 662-mg, and 882-mg extended-release injectable suspension.
Warnings/Contraindications: Increased incidence of cerebrovascular adverse reactions in elderly patients with dementia related psychosis. Neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, orthostatic hypotension, leukopenia, neutropenia, agranulocytosis, seizures, and cognitive and motor impairment may occur while taking this drug.
Notes: For patients who are naïve to aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with aripiprazole lauroxil. Dose adjustments are required for patients taking CYP3A4 and CYP2D6 inhibitors or CYP3A4 inducers for more than 2 weeks. Adjust the dose in patients who are known poor metabolizers of CYP2D6.

Idarucizumab (Praxbind, Boehringer Ingelheim)
Pharmacology: Humanized monoclonal antibody fragment that binds dabigatran and its acylglucuronide metabolites.
Indication: For patients treated with Pradaxa (dabigatran) when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.
Adverse Drug Reactions: Headache, hypokalemia, delirium, constipation, pyrexia, and pneumonia.
Dose: The recommended dose is 5 g (provided as 2 separate vials of 2.5 g each).
Formulation: 2.5 g/50 mL solution for injection.
Warnings/Contraindications: Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. In patients with elevated coagulation parameters and reappearance of clinically relevant bleeding or requiring a second emergency surgery/urgent procedure, an additional 5g dose idarucizumab may be considered. Patients with hereditary fructose intolerance may be at serious risk of adverse reactions.

Patiromer (Veltassa, Relypsa Inc)
Pharmacology: Potassium binder.
Indication: For the treatment of hyperkalemia that is non-emergent and not life threatening.
Adverse Drug Reactions: Constipation, hypomagnesaemia, diarrhea, nausea, abdominal discomfort and flatulence.
Dose: The recommended starting dose is 8.4 g orally once daily with food. Titrate dose by 8.4 g daily at one-week intervals until desired serum potassium level is reached.
Formulation: 8.4-g, 16.8-g, and 25.2-g powder packets.
Warnings/Contraindications: May cause worsening gastrointestinal motility and hypomagnesaemia.
Notes: This product binds to other orally administered medications and should be administered 6 hours before or 6 hours after other oral medications.

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Asfotase alfa (Strensiq, Alexion Pharm)
Pharmacology: Tissue nonspecific alkaline phosphatase.
Indication: For the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).
Adverse Drug Reactions: Injection site reactions, lipodystrophy, ectopic calcifications and hypersensitivity reactions
Dose: For perinatal/infantile- and juventile-onset HPP the starting dose is 2 mg/kg subcutaneously three times per week, or 1 mg/kg six times per week.
Formulation: 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL or 80 mg/0.8 mL solution for injection.
Warnings/Contraindications: Hypersensitivity reactions can occur. Rotate the site of injection and use proper technique to avoid lipodystrophy. Ectopic calcifications of the eye and kidney have occurred.
Notes: The 80 mg/0.8 mL concentration should not be used in pediatric patients weighing less than 40 kg due to the potential for achievement of lower systemic concentrations.

Trabectedin (Yondelis, Janssen Prods.)
Pharmacology: Alkylating agent.
Indication: For the treatment of unresectable or metastatic liposarcoma or leiomyosarcoma in the patients who received prior anthracycline containing regimens.
Adverse Drug Reactions: Nausea, fatigue, vomiting, constipation, decreased appetite, diarrhea, peripheral edema, dyspnea, headache, neutropenia, increased ALT, thrombocytopenia, anemia, increased AST, and increased creatine phosphokinase.
Dose: Administer 1.5 mg/m^2 IV over 24 hours every 3 weeks through a central venous line.
Formulation: 1-mg lyophilized powder for injection.
Warnings/Contraindications: Neutropenic sepsis, rhabdomyolysis, hepatotoxicity, cardiomyopathy, and embryofetal toxicity can occur during treatment with this agent.
Notes: Premedicate with dexamethasone 20mg IV, 30 minutes before each infusion. Avoid use with CYP3A4 inducers and inhibitors.

NEW DRUG FORMULATIONS

Morphine sulfate (Morphabond, Inspiron Delivery Technologies LLC)
Pharmacology: Opioid agonist.
Indication: The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Dosage form: 15-mg, 30-mg, 60-mg or 100-mg extended release tablets.
Dose: Morphabond100-mg tablets, a single dose greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established. For opioid-naïve and opioid non-tolerant patients, initiate with 15 mg tablets orally every 12 hours.

Calcipotriene; Betamethasone diproprionate (Enstilar, Leo Pharma AS)
Pharmacology: Combination vitamin D analog and corticosteroid.
Indication: For the topical treatment of plaque psoriasis in patients 18 years of age and older.
Dosage form: 0.005%/0.064% foam.
Dose: Apply foam to affected area(s) once daily for up to 4 weeks.

Amphetamine (Dyanavel XR, Tris Pharma Inc.)
Pharmacology: CNS stimulant.
Indication: Prescribed for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
Dosage form: 2.5 mg/mL extended-release oral suspension.
Dose: In children 6 years of age and older, recommended starting dose is 2.5 mg or 5 mg once daily in the morning. Dosage may be increased in increments of 2.5 mg to 10 mg per day every 4 to 7 days until optimal response is obtained.

Dexmedetomidine hydrochloride (Dexmedetomidine hydrochloride, HQ Specialty Pharma)
Pharmacology: Central alpha-2 adrenergic agonist.
Indication: Used for sedation of non-intubated patients prior to and/or during surgical and other procedures.
Dosage form: 400 mg/4 mL or 1000 mg/10 mL solution for injection supplied in a multiple-dose vial.
Dose: Dilute in 0.9% Sodium Chloride Injection to a concentration of 4 mcg/mL prior to administration; administer intravenously using a controlled infusion device.

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Vivlodex (Meloxicam, Iroko Pharms LLC)
Pharmacology: Nonsteroidal anti-inflammatory drug.
Indication: For the management of osteoarthritis pain.
Dosage form: 5-mg or 10-mg oral capsule.
Dose: Start with 5 mg orally once daily. May increase dose to 10 mg in patients who require additional analgesia. Meloxicam capsules are not directly interchangeable with other formulations of meloxicam.

Irinotecan liposome (Onivyde, Merrimack Pharms Inc.)
Pharmacology: Topoisomerase inhibitor.
Indication: Medication given in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.
Dosage form: 43 mg/10 mL solution for injection in a single-dose vial.
Dose: Recommended dose is 70 mg/m^2 IV over 90 minutes every 2 weeks. Recommended starting dose for patients homozygous for UGT1A1*28 is 50 mg/m^2 every 2 weeks. There is no recommended dose for patients with serum bilirubin above the upper limit of normal.

Buprenorphine (Belbuca, Endo Pharms Inc)
Pharmacology: Partial opioid agonist.
Indication: The management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Dosage form: 75-mcg, 150-mcg, 300-mcg, 450-mcg, 600-mcg, 750-mcg, and 900-mcg buccal film.
Dose: For opioid-naïve patients, initiate therapy with 75 mcg once daily or every 12 hours for at least 4 days before increasing dose to 150 mcg every 12 hours. To convert from other opioids to buprenorphine, taper current daily opioid dose to 30 mg oral morphine sulfate equivalents (MSE) or less prior to initiating therapy. For patients taking less than 30 mg oral MSE, initiate therapy with 75 mcg once daily or every 12 hours, for patients taking between 30 mg and 89 mg oral MSE, initiate therapy with 150 mcg every 12 hours following analgesic taper, for patients taking between 90 mg and 160 mg oral MSE, initiate therapy with 300 mcg every 12 hours following analgesic taper and for patients taking greater than 160 mg oral MSE, consider an alternate analgesic.

Acetaminophen (Acetaminophen, Fresenius Kabi USA)
Pharmacology: Non-steroidal anti-inflammatory drug.
Indication: Management of mild to moderate pain or moderate to severe pain with adjunctive opioid analgesics and reduction of fever.
Dosage form: Injection for IV, each 100 mL flexible plastic container has 1,000 mg acetaminophen.
Dose: Adults and adolescents weighing 50 kg and over, administer 1,000 mg every 6 hours or 650 mg every 4 hours to a maximum of 4,000 mg per day. Adults and adolescents weighing less than 50 kg administer 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. Children 2 to 12 years of age administer 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. The minimum-dosing interval is 4 hours.

Lonsurf (Trifluridine/Tipiracil, Taiho Oncology Inc)
Pharmacology: Nucleoside metabolic inhibitor/thymidine phosphorylase inhibitor.
Indication: For the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatic-, and irinotecan-based chemotherapy, and anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
Dosage form: 15-mg/6.14-mg and 20-mg/8.19-mg tablets.
Dose: The recommended dose is 35 mg/m^2/dose orally twice daily on days 1 through 5 and days 8 through 12 of each 28-day cycle. Take trifluridine/tipitacil within 1 hour of completing morning and evening meals.

Seebri Neohaler (Glycopyrrolate, Novartis)
Pharmacology: Anticholinergic agent.
Indication: For the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.
Dosage form: 15.6-mcg dry powder capsules for oral inhalation.
Dose: One inhalation of the contents of one capsule twice daily.

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Utibron Neohaler (Indacaterol/glycopyrrolate, Novartis)
Pharmacology: Long-acting beta$_2$-adrenergic antagonist/anticholinergic agent.
Indication: For the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.
Dosage form: 27.5/15.6-mcg dry powder capsules for oral inhalation.
Dose: One inhalation of the contents of one capsule twice daily.

NEW DRUG INDICATIONS

Pembrolizumab (Keytruda, Merck & Co)
Pharmacology: Programmed death receptor-1 (PD-1) blocking antibody.
New Indication: For the treatment of advanced non-small cell lung cancer in patients with tumors that expresses programmed death receptor-1 (PD-L1) and whose disease has progressed after other treatments.
Dose: The recommended dose is 2 mg/kg IV infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity

Nivolumab (Opdivo, Bristol-Myers Squibb)
Pharmacology: Programmed death receptor-1 (PD-1) blocking antibody.
New Indication: For the treatment of advanced non-squamous, non-small cell lung cancer in patients whose disease progressed during or after platinum-based chemotherapy.
Dose: Administer IV infusion over 60 minute. For patients with metastatic non-small cell lung cancer, give nivolumab 3 mg/kg every 2 weeks.

Prepared by: Melissa Patel and Whitney Bernreuter, Pharm.D. Candidates

Reviewed by: Maisha Kelly Freeman, Pharm.D, MS, BCPS, FASCP