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

Deutetrabenazine (Austedo, Teva Pharmaceuticals)
Pharmacology: Vesicular monoamine transporter 2 (VMAT2) inhibitor.
Indication: Chorea associated with Huntington's disease.
Adverse Drug Reactions: Somnolence, diarrhea, dry mouth, and fatigue.
Dose: The starting dose is 6 mg once daily and the dose can be titrated to a maximum of 48 mg (24 mg twice daily).
Formulation: Tablets: 6 mg, 9 mg, and 12 mg.
Warnings/Contraindications: Suicidal or untreated / inadequately treated depression; hepatic impairment, taking MAOIs (e.g., reserpine or tetrabenzaine).
Notes: Adminster with food. Swallow tablets whole. If deutetrabenazine is used with strong CYP2D6 inhibitors, the maximum recommended dose is 36 mg/day or 18 mg twice daily.

Valbenazine (Ingrezza, Neurocrine Biosciences, Inc.)
Pharmacology: Vesicular monoamine transporter 2 (VMAT2) inhibitor.
Indication: Treatment of adults with tardive dyskinesia.
Adverse Drug Reactions: Somnolence.
Dose: The initial dose if 40 mg once daily and the dose can be increased to 80 mg once daily.
Formulation: Capsules, 40 mg.
Warnings/Contraindications: QT prolongation, somnolence.
Notes: Patients with moderate or severe hepatic impairment should receive 40 mg once daily. Dose reduction should be considered in patients who are CYP2D6 poor metabolizers.

Infliximab-Abda (Renflexis, Merck)
Pharmacology: Biosimilar to Infliximab (Remicade); Tumor necrosis factor.
Indication: Crohn's disease, pediatric crohn's disease, ulcerative colitis, rheumatoid arthritis (in combination with metrotrexate), ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.
Adverse Drug Reactions: Infections, infusion-related reactions, headache, and abdominal pain.
Dose: The dosage varies from 5 mg/kg to 10 mg/kg depending on the disease state.
Formulation: Injection-100 mg in 20 mL via for intravenous infusion.
Warnings/Contraindications: Serious infection, invasive fungal infections, malignancies, Hepatitis B virus reactivation, hepatotoxicity, heart failure, cytopenas, hypersensitivity, demyelinating disease, lupus-like syndrome, and live vaccines or therapeutic infectious agents.
Notes: Increased risk of serious infection with anakinra or abatacept.

Cerliponase Alfa (Brineura, BioMarin Pharmaceutical, Inc.)
Pharmacology: Hydrolytic lysosomal N-terminal tripeptidyl peptidase.
Indication: Slow the loss of ambulation in symptomatic pediatric patients aged 3 and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2).
Adverse Drug Reactions: Pyrexia, ECG abnormalities, decreased CSF protein, vomiting, seizures, hypersensitivity, increased CSF protein, hematoma, headache, irritability, pleocytosis, device-related infection, bradycardia, feeling jittery, and hypotension.
Dose: The recommended dose is 300 mg every other week.
Formulation: Injection: 150 mg/5 mL.
Warnings/Contraindications: Acute intraventricular access device-related complications; patients with ventriculoperitoneal shunts.
Notes: Cardiovascular adverse reactions can occur with therapy. Monitor ECG.

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Midostaurin (Rydapt, Novartis Pharmaceuticals)
Pharmacology: Kinase inhibitor.
Indication: Newly diagnosed acute myeloid leukemia that is FLT3 mutation-positive; aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia.
Adverse Drug Reactions: Febrile neutropenia, nausea, mucositis, vomiting, headache, petechiae, etc.
Dose: 500-100 ng twice daily, depending on the indication.
Formulation: Capsules 25 mg.
Warnings/Contraindications: Embryo-fetal toxicity.
Notes: Strong 3A4 inhibitors may cause an increase in exposure to midostaurin and its active metabolites. Avoid concomitant use with strong CYP3A4 inducers.

Abaloparatide (Tymlos, Radius Health, Inc.)
Pharmacology: Human parathyroid hormone related peptide.
Indication: Treatment of postmenopausal women with osteoporosis at high risk of fracture.
Adverse Drug Reactions: Hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain.
Dose: The recommended dose is 80 mcg subcutaneously once daily.
Formulation: Injection: 3120 mcg/1.56 mL in a single-patient-use prefilled spin.
Warnings/Contraindications: Orthostatic hypotentsion, hypercalcemia, hypercalciuria, and urothiasis.
Notes: Supplemental calcium and vitamin D should be taken while administering abaloparatide.

Brigatinib (Alunbrig, Aria Pharmaceuticals)
Pharmacology: Kinase inhibitor.
Indication: Lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer who have progressd on or are intolerant to crizotinib.
Adverse Drug Reactions: Nausea, diarrhea, faigue; cough, and headache.
Dose: The recommended dose is 90 mg daily for the first 7 days.
Formulation: Tablets, 30 and 60 mg.
Warnings/Contraindications: Intertitial lung disease, hypertension, and bradycardia.
Notes: Potential drug-dug interaction with CYP3A inhbitrs, inducers, and substrates.

NEW DRUG FORMULATIONS

Clindamycin / Sodium Chloride Acetate (Clindamycin / 0.9% Sodium Chloride, Celerity Pharmaceuticals, LLC)
Pharmacology: Lincosamid antibacterial.
Indication: Several infections including lower respiratory tract infections; skin and skin structure infections, gynecological infections, etc.
Dosage form: Injection containing 300 mg/40 mL, 600 mg/50 mL, and 900 mg/50 mL that contains 300, 600, or 900 mg clindamycin.
Dose: Various.

Methotrexate (Xatmep, Silvergate Pharmaceuticals, Inc.)
Pharmacology: Folate analog metabolic inhibitor.
Indication: Treatment of pediatric patietns with acute lymphoblastic leukemia (ALL); management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant or had an inadequate response to first-line therapy.
Dosage form: Oral solution, 2.5 mg/mL.
Dose: Recommended dose for ALL is 20 mg/m^2 once weekly and for pJIA is 10 mg/m^2 once weekly.

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