CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY 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 (205) 726-2659.

NEW DRUG APPROVALS

Rolapitant (Varubi, Tesaro Inc.)
Pharmacology: Substance P/neurokinin 1 (NK1) receptor antagonist.
Indication: For the prevention of delayed nausea and vomiting in conjunction with other antiemetics in patients receiving emetogenic cancer chemotherapy.
Adverse Drug Reactions: Common adverse reactions include neutropenia, hiccups, abdominal pain, decreased appetite, dizziness, dyspepsia, urinary tract infection (UTI), stomatitis, and anemia.
Dose: 180mg administered 1-2 hours prior to chemotherapy.
Formulation: 90-mg oral tablet.
Warnings/Contraindications: Rolapitant inhibits CYP2D6 for 7 days or longer after administration. Avoid concomitant use with CYP2D6 substrates, especially pimozide due to risk of QT prolongation. Rolapitant is contraindicated with thioridazine; coadministration may lead to QT prolongation or Torsades de Pointes.
Notes: Rolapitant is also a BCRP / P-gp inhibitor and CYP3A4 substrate; it is not recommended for use with strong CYP3A4 inducers.

Uridine triacetate (Xuriden, Wellstat Therapeutics Corp)
Pharmacology: Uridine supplementation.
Indication: Hereditary orotic aciduria/uridine monophosphate synthase deficiency.
Adverse Drug Reactions: None noted in clinical trial of four patients.
Dose: Starting dosage of 60 mg/kg daily and may be increased to120 mg/kg daily for insufficient efficacy. Do not exceed 8 g per day.
Formulation: Oral granules in 2-g packets.
Warnings/Contraindications: None listed.
Notes: Administer the dose with food (e.g., applesauce, pudding or yogurt) or in milk or infant formula.

Cariprazine (Vraylar, Forest Labs LLC)
Pharmacology: Atypical antipsychotic.
Indication: Treatment of schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder.
Adverse Drug Reactions: Common adverse events include extrapyramidal symptoms, akathisia, and weight gain. Potentially serious adverse events include neuroleptic malignant syndrome, tardive dyskinesia, leukopenia, neutropenia, agranulocytosis, may lower the seizure threshold, hyperglycemia, dyslipidemia, and body temperature dysregulation.
Dose: For management of schizophrenia the recommended dose ranges from 1.5 mg to 6 mg once a day.
For treatment of bipolar I disorder episodes doses range from 3 mg to 6 mg once a day.
Start with 1.5mg on day one for either indication, can increase to 3 mg on day 2 and adjust by 1.5 to 3 mg daily depending on response and tolerance.
Formulation: 1.5-mg, 3-mg, 4.5-mg, and 6-mg oral capsule.
Warnings/Contraindications: Increased mortality and cerebrovascular adverse events in elderly patients with dementia related psychosis. Neuroleptic malignant syndrome, tardive dyskinesia, infections due to hematologic changes, lower seizure threshold, body temperature dysregulation, and dysphagia may cause serious adverse events.
Do not use cariprazine with CYP3A4 inducers.
Notes: Cariprazine is activated and eliminated by CYP3A4 and the dose must be adjusted if the patient is on a strong 3A4 inhibitor. Some adverse reactions may be delayed for several weeks due accumulation of metabolites.

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Trifluridine-tipiracil (Lonsurf, Taiho Oncology Inc)
Pharmacology: Nucleoside metabolic inhibitor- thymidine phosphorylase inhibitor.
Indication: Metastatic colorectal cancer previously treated with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy; anti-VEGF (vascular endothelial growth factor) biologic therapy, or, if RAS-wild type, an anti-EGFR (epidermal growth factor receptor) therapy.
Adverse Drug Reactions: Common adverse effects include anemia, neutropenia, asthenia/fatigue, nausea, thrombocytopenia, decreased appetite, diarrhea, vomiting, abdominal pain, and pyrexia.
Dose: Take 35 mg/m^2 orally twice daily on Days 1 through 5 and Days 8 through 12 of each 28-day cycle.
Formulation: Oral tablets in 15 mg trifluridine/6.14 mg tipiracil or 20 mg trifluridine/8.19 mg tipiracil.
Warnings/Contraindications: Embryo-fetal toxicity and severe myelosuppression including anemia, neutropenia, thrombocytopenia, and febrile neutropenia may occur.
Notes: No studies have been performed to determine the effects of renal impairment on pharmacokinetics or pharmacodynamics, but an increased incidence of severe adverse drug reactions was noted for patients with moderate renal impairment.

Insulin degludec (Tresiba, Novo Nordisk Inc)
Pharmacology: Long-acting human insulin analog.
Indication: To improve glycemic control in adults with diabetes mellitus.
Adverse Drug Reactions: Common reactions include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, and weight gain. Other serious reactions include hypokalemia and upper respiratory tract infections.
Dose: Dose is individualized based on patient needs, disease type, clinical goal, and glucose monitoring results.
Formulation: 100 units/mL or 200 units/mL 3mL FlexTouch® pens for subcutaneous injection.
Warnings/Contraindications: Hyperglycemia or hypoglycemia during regimen changes, hypoglycemia, life-threatening hypersensitivity, life-threatening hypokalemia, and fluid retention or heart failure may occur if used with thiazolidinediones.
Notes: Not for use in diabetic ketoacidosis or with anti-adrenergic drugs.

Insulin degludec/Insulin aspart (Ryzodeg® 70/30, Novo Nordisk Inc)
Pharmacology: Mix of long and short acting insulin.
Indication: To improve glycemic control in adults with diabetes.
Adverse Drug Reactions: Common reactions include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritis, rash, edema, and weight gain. Other serious reactions include hypokalemia and upper respiratory tract infections.
Dose: Dose is individualized based on patient needs, disease type, clinical goal, and glucose monitoring results.
Formulation: 70 units of insulin degludec and 30 units of insulin aspart/mL of solution in a 3mL FlexTouch® pen.
Warnings/Contraindications: Hyperglycemia or hypoglycemia during regimen changes, hypoglycemia, life-threatening hypersensitivity, life-threatening hypokalemia, and fluid retention or heart failure may occur if used with thiazolidinediones.
Notes: Not for use in diabetic ketoacidosis or with anti-adrenergic drugs.

NEW DRUG FORMULATIONS

Aspirin (Durlaza, New Haven Pharmaceuticals, Inc)
Pharmacology: Non-steroidal anti-inflammatory drug.
Indication: Reduce the risk of death and myocardial infarction in patients with chronic coronary artery disease and to reduce the risk of death and recurrent stroke in patients who had ischemic stroke or transient ischemic attack.
- Not for use in acute treatment of myocardial infarction, before percutaneous coronary intervention, or in other cases where rapid onset of action is required.

Dosage form: Extended release 162.5-mg oral capsule.
Dose: Take 162.5 mg at the same time once per day with a full glass of water.

Tiotropium bromide (Spiriva® Respimat®, Boehringer Ingelheim)
Pharmacology: Inhaled anticholinergic.
Indication: Once daily maintenance of asthma or COPD to reduce bronchospasms or exacerbations.
- Not for use in acute bronchospasm treatment.

Dosage form: Respimat® inhaler.
Dose: 1.25 mcg or 2.5 mcg per actuation.

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Fluorouracil (Tolak, Hill Dermaceuticals)
Pharmacology: Nucleoside metabolic inhibitor.
Indication: Topical treatment of actinic keratosis lesions of the face, ears, and scalp.
Dosage form: 4% fluorouracil cream.
Dose: Use an amount sufficient to cover the affected area and gently massage into the skin.

NEW DRUG INDICATIONS

Adilimumab (Humira, Abbvie Inc.)
Pharmacology: Tumor necrosis factor (TNF) blocker
New Indication: For the treatment of hidradentitis supprativa.
Dose: 160 mg on day 1 or divided dose on days 1 and 2 followed by 80 mg daily for 2 weeks then 40 mg weekly starting on day 29.

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