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

Mogamulizumab-KPKC (Poteligeo, Kyowa Kirin)
Pharmacology: CC Chemochine receptor type 4 (CCR4)-directed monoclonal antibody.
Indication: Relapsed or refractory mycosis fungiodes or Sezary syndrome after at leas one prior therapy.
Adverse Drug Reactions: Rash, infusion-related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection.
Dose: 1 mg/kg intravenous infusion administerd over at least 60 minutes on days 1, 8, 15, and 22 on the first 28-day cycle and on days 1 and 15 of each subsequent cycle.
Formulation: Injection: 20 mg/5 mL.
Warnings/Contraindications: Dermatologic toxicity, infusion reactions, infections, autoimmune complications, and complications of allogenic HSCT after mogamulizumab administration.
Notes: There is a possibiilty for immunogenic sensitivity.

Migalastat Hydrochloride (Galafold, Amicus Therapeutics US, Inc.)
Pharmacology: Alpha-galactosidase A pharmacological chaperone.
Indication: Treatment of adults with confirmed diagnosis of Fabry disease.
Adverse Drug Reactions: Headache, nasopharyngitis, nausea, and pyrexia.
Dose: One capsule every other day at the same time each day.
Formulation: Capsule, 123 mg migalastat.
Warnings/Contraindications: None listed.
Notes: Take on an empty stomach.

Segesterone Acetate; Ethinyl estradiol (Annovera, The Population Council, Inc.)
Pharmacology: Progestin/estrogen combination hormonal contraceptive (CHC).
Indication: Contraception to prevent pregnancy.
Adverse Drug Reactions: Headache/migraine; nausea/vomiting; vulvovaginal mycotic infection/candidiasis; abdominal pain lower/upper; dysmenorrhea; vaginal discharge; urinary tract infection; breast tenderness/pain/discomfort; bleeding irregularities including metorrhagia, diarrhea, genital pruritus.
Dose: 103 mg/17.4 mg.
Formulation: Silicone elastomer vaginal system containing 103 mg of segesterone and 17.4 mg ethinyl estradiol.
Warnings/Contraindications: High risk of arterial or venous thrombotic diseases; current or history of breat cancer or other estrogen-or-progestin-sensitive cancer; liver tumors; undiagnosed abnormal uterine bleeding; use of Hepatitis C drug combinations.
Notes: Drugs or herbal products that induce CYP3A4 may decrease the effectiveness of segesterone acetate/ethinyl estradiol.

Patisiran (Onpattro, Alnlyman Pharma, Inc.)
Pharmacology: Transthyretin-directed small interfering RNA.
Indication: Treatment of the polyneuropathy of hereditary transthyrectin-mediated amyloidsis in adults.
Adverse Drug Reactions: Upper respiratory tract infections and infusion-related reaction.
Dose: Patients <100 kg, the recommended dose is 0.3 mg/kg every 3 weeks by intravenous infusions; for patients weighing >100 kg, the recommended dosage is 30 mg.
Formulation: Injection: 10 mg/5mL.
Warnings/Contraindications: None listed.
Notes: May need to supplement with vitamin A levels if serum vitamin A levels are reduced.

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Stiripentol (Diacomit, Biocodex SA)
Pharmacology: Anticonvulsant.
Indication: Treatment of seizures associated with Dravet syndrome in patients >2 years taking clonazepam.
Adverse Drug Reactions: Somnolence, decreased, appetite, agitation, ataxia, weight decreased, hypotonia, nausea, tremor dysrthria, and insominia.
Dose: 50 mg/kg/day, administered by mouth in 2-3 divided doses.
Formulation: Capsule: 250 or 500 mg. Powder for oral suspension: 250 or 500 mg.
Warnings/Contraindications: Somnolence, decrased appetite and decreased weight, neutropenia and thrombocytopenia, withdrawal; suicidal behavior and Ideation.
Notes: Capsules should not be broken.

Cenegermin-BKBJ (Oxervate, Dompe Farmaceuticals)
Pharmacology: Recombinant human nerve growth factor.
Indication: Neurotrophic keratitis.
Adverse Drug Reactions: Eye pain, ocular hyperemia, eye inflammation, and increased lacrimation.
Dose: One drop in the affected eye(s), 6 times/day at 2-hour intervals for eight weeks.
Formulation: Ophthalmic solution, 0.002%.
Warnings/Contraindications: Remove contact lenses before applying and wait for 15 minutes as after instillation before reinsertion.
Notes: Administer subsequent eye drops 15 minutes after insertion of the drops.

Lanadelumab (Takhzyro, Dyax corp.)
Pharmacology: Plasma kallikrein inhbitior.
Indication: Prophylaxis to prevent attacks of hereditary angioedema in patients ≥12 years.
Adverse Drug Reactions: Upper respiratory infections, headache, rash, myalgia, dizziness, and diarrhea.
Dose: 300 mg every 2 weeks. Consider dosing every 4 weeks for some patients.
Formulation: Injection: 300 mg/2mL.
Warnings/Contraindications: None listed.
Notes: Landelumab is administed subcutaneously.

Eravacycline (Xerava, Tetraphase Pharms, Inc.)
Pharmacology: Tetracycline class antibacterial.
Indication: Complicated intra-abdominal infections in patients 18 years of age or older.
Adverse Drug Reactions: Infusion site reactions, nausea, and vomiting.
Dose: 1 mg/kg by intravenous infusion over 60 minutes every 12 hours for a total duration of 4-14 days.
Formulation: Powder for injection-50 mg.
Warnings/Contraindications: Hypersensitivity reactions, tooth discoloration and enamel hypoplasia; inhibition of bone growth, and *C. difficile* associated diarrhea.
Notes: Dosage reduction may be necessary for patients with severe hepatic impairment or concomitant use of strong cytochrome P450 enzyme inducers.

Doravirine (Pifeltro, Merck Inc)
Pharmacology: Non-nucleoside reverse transcriptase inhibitor (NNRTI).
Indication: Treatment of HIV-1 infection in antiretroviral naïve patients.
Adverse Drug Reactions: Nausea, dizziness, headache, fatigue, diarrhea, abdominal pain, and abnormal dreams.
Dose: One tablet taken orally once daily with or without food.
Formulation: Tablets, 100 mg.
Warnings/Contraindications: Coadministration with drugs that are strong cytochrome P450 3A4 enzyme inducers.
Notes: Dosage adjustment with rifabutin coadministration is required.

Doravirine; Lamivudine; Tenofovir Disoproxil Fumarate (Delstrigo, Merck)
Pharmacology: Combination of non-nucleoside reverse transcriptase inhibitor (NNRI) and nucleoside analogue reverse transcriptase inhibitor).
Indication: Treatment of HIV-1 infection in antiretroviral naïve patients.
Adverse Drug Reactions: Dizziness, nausea, and abnormal dreams.
Dose: One tablet taken orally once daily with or without food.
Formulation: Tablets: 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate.
Warnings/Contraindications: Coadministration with strong CYP3A4 enzyme inducers and hypersensitivity reactions.
Notes: Coadministration with other HIV drugs is contraindicated.

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NEW DRUG FORMULATIONS

Lumacaftor/Ivacaftor (Orkambi, Vertex Pharms)
Pharmacology: Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator.
Indication: Treatment of cystic fibrosis in patients age 2 years or older who are homozygous for the F508del mutation in the CFTR gene.
Dosage form: Tablets, lumacaftor 100 mg and ivacftor 125 mg; lumacaftor 200 mg and ivacftor 125 mg; Oral granules-containing lumacaftor 100 mg and ivacaftor 125 mg; lumacaftor 150 mg and ivacaftor 188 mg.
Dose: Dosage is based on weight. Pediatric patients age 2-5 years weighing <14 kg: one packet of granules mixed with 1 teaspoon of soft food or liquid every 12 hours.

Methylphenidate hydrochloride (Jornay, Ironshore Pharma Dev, Inc.)
Pharmacology: Central nervous system (CNS) stimulant.
Indication: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.
Dosage form: Extended-release capsules-20 mg, 40 mg, 60 mg, 80 mg, and 100 mg.
Dose: Recommended dose for patients 6 years and older is 20 mg daily in the evening.

Tafenoquine (Arakoda, 60 Degrees Pharms, LLC)
Pharmacology: Antimalarial.
Indication: Prophylaxis of malria in adults.
Dosage form: Tablets: 100 mg.
Dose: Loading regimen is to be given for each of the 3 days before travel to a malarious area-200 mg (2 of the 100 mg tablets) once daily for 3 days. Maintenance regimen and terminal prophylaxis regimen are required.

Lamivudine; neirapine; zodovudine (Micro labs, LTD)
Pharmacology: Combination of two nucleoside analogue reverse transcriptase inhibitors and one non-nucleoside analogue reverse transcriptase inhibitor.
Indication: Indicated alone as a complete regimen or in comination with other antiretroviral drugs for the treatment of HIV-1 infection.
Dosage form: Tablets: 150 lamivudine; 200 mg nevirapine,a nd 300 mg zidovudine.
Dose: Initial dose is 200 mg once daily.

Cyclosprine ophthalmic solution (Cequa, Sun Pharma Global)
Pharmacology: Calcineurin inhibitor immunosuppressant.
Indication: Increase tear production in patients with keratoconjunctivitis sicca (dry eye).
Dosage form: Ophthalmic solution containing cyclosprone 0.9 mg/mL.
Dose: Instill one drop twice daily into each eye.

Efavirenz; lamivudine; tenofovir; disoproxil fumarate (Aurobindo Pharma, LTD)
Pharmacology: Non-nucleoside analogue reverse transcriptase inhibitor and nucleotide reverse transcriptase inhibitor.
Indication: Treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg.
Dosage form: Tablets- 600 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil).
Dose: One tablet taken orally once daily at bedtime.

Loteprednol Etabonate (Inveltys, Kala Pharms, Inc.)
Pharmacology: Corticosteroid.
Indication: Post-operative inflammation and pain following ocular surgery.
Dosage form: Ophthalmic suspension containing 10 mg/mL of loteprednol etabonate.
Dose: Instill one to two drops into the affected eye twice daily beginning the day after surgery and continuing for 2 weeks.

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New drug approvals, formulations, and indications. *New Drug FAX Sheet.* 2018 September 17;23(9):1-3.