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Volume 20 (Issue 16)

August 17, 2015

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

### **Brexipiprazole (Rexulti, Novartis Pharms Corp)**

**Pharmacology:** Dopamine system stabilizer, atypical antipsychotic.

**Indication:** Treatment of schizophrenia and as adjunctive treatment of major depression.

**Adverse Drug Reactions:** Akathisia, increased triglycerides, and weight gain are all common adverse reactions.

**Dose:** Take 1 mg by mouth once daily for schizophrenia- may increase to 4 mg over 8 days of therapy. Take ½ to 1 mg once daily as adjunctive therapy for major depression- obtaining a target dose of 2 mg once daily.

**Formulation:** Oral tablets (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg).

**Warnings/Contraindications:** Neuroleptic malignant syndrome, strokes in elderly patients, tardive dyskinesia, metabolic changes, leukopenia, neutropenia, agranulocytosis, orthostatic hypotension, and seizures.

**Notes:** May take with or without regard to food. Avoid combination with amisulpride, azelastine (nasal), conivaptan, fusidic acid, idelalisib, metoclopramide, orphenadrine, paraldehyde, sulpiride, and thalidomide. Inhibition of CYP2D6 and/or CYP3A4 may increase brexipiprazole concentrations.

### **Sonidegib (Odomzo, Novartis Pharms Corp)**

**Pharmacology:** Hedgehog pathway inhibitor, an antineoplastic agent.

**Indication:** Basal cell carcinoma.

**Adverse Drug Reactions:** Common occurring adverse reactions include: fatigue, headache, pain, alopecia, hyperglycemia, weight loss, increased serum ALT/AST, increased amylase, dysgeusia, increased serum lipase, nausea, diarrhea, decreased appetite, abdominal pain, vomiting, anemia, lymphocytopenia, increased creatinine phosphokinase, muscle spasm, musculoskeletal pain, and myalgia.

**Dose:** Take 200 mg by mouth (on empty stomach 1 hour before or 2 hours after meal) until disease progression or unacceptable toxicity occurs.

**Formulation:** 200-mg oral tablets.

**Warnings/Contraindications:** The following are black box warnings associated with this agent: contraception requirements, intrauterine fetal death, male-mediated teratogenicity, pregnancy, pregnancy testing, and reproductive risk..

**Notes:** Take this medication on an empty stomach. Do not crush, cut, or chew- swallow whole. Sonidegib is a major substrate of CYP3A4, caution is advised when using any inhibitors of such enzyme. Patients cannot donate blood or blood products during treatment with sonidegib and for at least 20 months after the last dose.

### **Alirocumab (Praluent, Sanofi Aventis)**

**Pharmacology:** Monoclonal antibody (IgG1isotype) that works by binding to proprotein convertase subtilisin kexin type 9.

**Indication:** Hypercholesterolemia.

**Adverse Drug Reactions:** Nasopharyngitis, injection site reactions, and influenza.

**Dose:** Inject 75 mg subcutaneously once every 2 weeks (increase to 150 mg if after 4 to 8 weeks, if adequate response is not achieved.

**Formulation:** Solutions for injection (75 mg and 150 mg).

**Warnings/Contraindications:** Hypersensitivity reactions have occurred with alirocumab. Discontinue treatment if serious hypersensitivity reactions occur.

**Notes:** Store in the refrigerator until 30 to 40 minutes prior to administration. Administer subcutaneously (rotating injection sites) into abdomen, thigh, or upper arm. Measure LDL-C levels within 4-8 weeks of initiating and changing the dosage of alirocumab.

### **Lumacaftor/ Ivacaftor (Orkambi, Vertex Pharms Inc)**

**Pharmacology:** Modulates the protein, cystic fibrosis transmembrane conductance regulator.

**Indication:** Cystic Fibrosis in patients age 12 years and older who are homozygous for the *F508del* mutation in the CFTR gene.

**Adverse Drug Reactions:** Dyspnea, nasopharyngitis, nausea, diarrhea, upper respiratory tract infections, fatigue, respiration abnormal, increased blood creatininephosphokinase, rash, flatulence, rhinorrhea, and influenza were the most common adverse reactions.

**Dose:** Take 2 tablets by mouth every 12 hours.

**Formulation:** Oral tablets (200 mg lumacaftor / 125 mg ivacaftor).

**Warnings/Contraindications:** Caution is advised in those patients with any form of liver injury, or in combination with drugs that are substrates of CYP3A.

**Notes:** Take this medication with fat containing foods. Reduce dose in patients with moderate or severe hepatic impairment. The dose should be reduced in patients taking strong CYP3A4 inhibitors.

### **Sacubitril; Valsartan (Entresto, Novartis Pharms Corp)**

**Pharmacology:** A combination of a neprilysin inhibitor and an angiotensin II receptor blocker.

**Indication:** Chronic Heart Failure. Reduces the risk of cardiovascular death and hospitalization for heart failure in NYHA Class II-IV patients with a reduced ejection fraction.

**Adverse Drug Reactions:** The common adverse reactions associated include hypotension, hyperkalemia, cough, dizziness, and renal failure.

**Dose:** Take 1 (49/51 mg) tablet by mouth twice daily (double dose after 2 weeks).

**Formulation:** Oral tablets (24 mg/ 26 mg, 49 mg/ 51 mg, 97 mg/ 103 mg).

**Warnings/Contraindications:** Monitor renal function and potassium levels. Observe for signs and symptoms. This block contains a black box warning for pregnancy, and should not be used during.

**Notes:** May take with or without regard to food.

## **NEW DRUG FORMULATIONS**

### **Adapalene; Benzoyl Peroxide (Epiduo Forte, Galderma Labs LP)**

**Pharmacology:** Combination of a specific retinoic acid nuclear receptor binder and an oxidizing agent.

**Indication:** Acne vulgaris

**Dosage form:** Topical gel. Comes in various pump sizes (15 g, 30 g, 45 g, 60 g, 70 g) in a strength of 0.3% adapalene / 2.5% benzoyl peroxide.

**Dose:** Apply a thin layer (pea-sized amount) to affected areas (face or trunk) once daily.

### **Ombitasavir; Paritaprevir; Ritonavir (Technivie, Abbvie Inc)**

**Pharmacology:** A combination of a NS5A inhibitor, NS3/4A protease inhibitor, and a CYP3A inhibitor.

**Indication:** Hepatitis C virus without cirrhosis (with administration of ribavirin).

**Dosage form:** Oral tablet (12.5 mg ombitasavir/ 75 mg paritaprevir/ 50 mg ritonavir).

**Dose:** Take two tablets by mouth every morning with a meal + ribavirin 600 mg by mouth twice daily.

## **NEW DRUG INDICATIONS**

### **Gefitinib (Iressa, Astrazeneca)**

**Pharmacology:** Tyrosine kinase inhibitor.

**New Indication:** Metastatic non-small cell lung cancer.

**Dose:** Take 250 mg by mouth once daily.

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