Current FDA-Related Drug Information

Approvals, Submission, and Important Labeling Changes for US Marketed Pharmaceuticals

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This monthly feature will help readers keep current on new drugs, new indications, dosage forms, and safety-related changes in labeling or use. Efforts have been made to ensure the accuracy of this information; however, if there are any questions, please let me know at bakerdan@wsu.edu.

Table 1. New drugs approved by the US Food and Drug Administration (FDA): January 18, 2013 through February 17, 2013

Alogliptin – Nesina (Takeda Pharmaceuticals)	
<i>Comparative agents:</i>	Dipeptidyl peptidase-4 inhibitors
<i>Indication:</i>	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
<i>Mechanism of action:</i>	Inhibition of the inactivation of incretin hormones that are involved with the regulation of serum glucose levels
<i>Common adverse effects:</i>	Nasopharyngitis, headache, and upper respiratory tract infection
<i>Dosage form & strength:</i>	Tablet: 6.25 mg, 12.5 mg, and 25 mg
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022271s000lbl.pdf
Alogliptin / metformin – Kazano (Takeda Pharmaceuticals)	
<i>Comparative agents:</i>	Dipeptidyl peptidase-4 inhibitors plus metformin
<i>Indication:</i>	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
<i>Mechanism of action:</i>	Inhibition of the inactivation of incretin hormones that are involved with the regulation of serum glucose levels; improves glucose tolerance
<i>Common adverse effects:</i>	Upper respiratory tract infection, nasopharyngitis, diarrhea, hypertension, headache, back pain, and urinary tract infection
<i>Dosage form & strength:</i>	Tablet: 12.5 mg alogliptin plus 500 mg or 1,000 mg metformin
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203414s000lbl.pdf
Alogliptin / pioglitazone – Oseni (Takeda Pharmaceuticals)	
<i>Comparative agents:</i>	Dipeptidyl peptidase-4 inhibitors plus thiazolidinediones
<i>Indication:</i>	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
<i>Mechanism of action:</i>	Inhibition of the inactivation of incretin hormones that are involved with the regulation of serum glucose levels; inhibition of hepatic gluconeogenesis
<i>Common adverse effects:</i>	Nasopharyngitis, back pain, and upper respiratory tract infection
<i>Dosage form & strength:</i>	Tablet: 12.5 mg alogliptin plus 15 mg, 30 mg, or 45 mg pioglitazone; 25 mg alogliptin plus 15 mg, 30 mg, or 45 mg pioglitazone
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022426s000lbl.pdf

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Table 1. New drugs approved by the US Food and Drug Administration (FDA): January 18, 2013 through February 17, 2013 (CONT.)

Mipomersen sodium – Kynamro (Genzyme Corporation)	
<i>Comparative agents:</i>	None
<i>Indication:</i>	Adjunct to lipid-lowering medications and diet to reduce low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)
<i>Mechanism of action:</i>	Inhibitor of apolipoprotein B-100 synthesis
<i>Common adverse effects:</i>	Injection site reactions, flulike symptoms, nausea, headache, and elevations in serum transaminases
<i>Dosage form & strength:</i>	Injection: single-use vial containing 1 mL of a 200 mg/mL solution
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203568s000lbl.pdf
Pomalidomide – Pomalyst (Celgene Corporation)	
<i>Comparative agents:</i>	None
<i>Indication:</i>	Patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy
<i>Mechanism of action:</i>	Inhibits proliferation and induces apoptosis of tumor cells along with the enhanced T cell- and natural killer cell-mediated immunity and inhibits the production of pro-inflammatory cytokines (eg, TNF- α and IL-6) by monocytes
<i>Common adverse effects:</i>	Fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper respiratory tract infections, back pain, and pyrexia
<i>Dosage form & strength:</i>	Capsules: 1 mg, 2 mg, 3 mg, and 4 mg
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204026lbl.pdf
Pooled plasma (human), solvent/detergent treated – Octaplas (Octapharma)	
<i>Comparative agents:</i>	Human plasma
<i>Indication:</i>	Replacement of multiple coagulation factors in patients with acquired deficiencies due to liver disease or undergoing cardiac surgery or liver transplant; plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP)
<i>Mechanism of action:</i>	Replacement therapy
<i>Common adverse effects:</i>	Pruritis, urticaria, nausea, headache, paresthesia
<i>Dosage form & strength:</i>	Solution for infusion: 45 to 70 mg human plasma protein/mL
<i>Product labeling:</i>	http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM336161.pdf
Sumatriptan – Zecuity (NuPathe)	
<i>Comparative agents:</i>	Sumatriptan, other routes
<i>Indication:</i>	Acute treatment of migraine with or without aura in adults
<i>Mechanism of action:</i>	Serotonin (5HT) 1b/1d receptor agonist
<i>Common adverse effects:</i>	Application site pain, paresthesia, pruritus, warmth, and discomfort
<i>Dosage form & strength:</i>	Iontophoretic transdermal system: 6.5 mg
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202278s000lbl.pdf

Table 2. New dosage forms and indications approved by the FDA: January 18, 2013 through February 17, 2013

Generic name	Brand name (Company)	Indication and comments
New dosage forms/strength/route of administration		
Oxybutynin	<i>Oxytrol for Women</i> (Merck)	“Rx to OTC switch” for women; <i>Oxytrol</i> will remain a prescription product for use in men with overactive bladder.
New indications		
Deferasirox	<i>Exjade</i> (Novartis)	Treat patients ages 10 years and older who have chronic iron overload resulting from non-transfusion-dependent thalassemia
Bevacizumab	<i>Avastin</i> (Genentech)	Metastatic colorectal cancer, with fluoropyrimidine-, irinotecan-, or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab-containing regimen.
Imatinib	<i>Gleevec</i> (Novartis)	Treatment of children with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia

Table 3. Agents pending FDA approval: January 18, 2013 through February 17, 2013

Generic name	Brand name (Company)	Indication and comments
Complete response letter: more information required		
Insulin degludec Insulin degludec / insulin aspart	<i>Tresiba</i> <i>Ryzodeg</i> (Novo Nordisk)	Additional cardiovascular data have been requested.
Recommended for approval by an FDA advisory panel		
Olodaterol	<i>Striverdi Respimat</i> (Boehringer Ingelheim)	Once-daily maintenance bronchodilatory treatment for airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema
Recommended for NON-approval by an FDA advisory panel		
Mannitol	<i>Bronchitol</i> (Pharmaxis)	Voted against approval of inhaled mannitol for the treatment of cystic fibrosis; advisory panel expressed concerns regarding safety and efficacy, especially in pediatric patients.
Agents scheduled for review by an FDA advisory panel		
Fluticasone furoate / vilanterol dry powder inhaler	<i>Breo Ellipta</i> (GlaxoSmithKline)	Long-term maintenance treatment of airflow obstruction and to reduce exacerbations in patients with chronic obstructive pulmonary disease

Table 4. New drug / biologics license applications filed by manufacturer: January 18, 2013 through February 17, 2013

Generic name <i>Brand name</i> (Company)	Comparative agents	Indication	Mechanism of action	Common adverse effects	Dosage form or route
Riociguat (Bayer HealthCare)	None	Treatment of pulmonary arterial hypertension and persistent/recurrent chronic thromboembolic pulmonary hypertension after surgical treatment or inoperable patients	Soluble guanylate cyclase (sGC) stimulator	Dyspepsia, headache, and hypotension	Oral

Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a

Generic name <i>Brand name</i> (Company)	Warning
Tolvaptan <i>Samsca</i> (Otsuka America Pharmaceuticals)	Potential liver injury associated with the use of tolvaptan http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm336669.htm?source=govdelivery

^aPractitioners are encouraged to check the FDA’s MEDWATCH Web site (<http://www.fda.gov/medwatch/safety.htm>) for updated information.