NEW DRUGS

Lacosamide (Vimpat) In Epilepsy
Lacosamide (Vimpat, UCB), an anti-epileptic drug, has been approved as an add-on agent for partial-onset seizures in patients 17 years of age and older. This approval was based on data from one phase 2 and two phase 3 randomized clinical trials.

Fewer than half (47%) of patients attain seizure control with their first medication, and more than 30% continue to experience seizures even with two or more drugs. Lacosamide should be considered for uncontrolled seizures.

Dosing should start at 50 mg twice daily and may be increased to a daily dose of 200 to 400 mg/day (the recommended dose) given in two divided doses.

Lacosamide will be available as oral tablets and as an intravenous (IV) infusion. It will be designated as a controlled substance.

(Source: FDA, October 29, 2008.)

Fesoterodine (Toviaz) For Overactive Bladder
Fesoterodine fumarate (Toviaz) has been approved to treat overactive bladder. Made by Schwarz Pharma and distributed by Pfizer Inc., the medication relaxes the smooth muscle tissue of the bladder, thus reducing urinary frequency, the urge to urinate, and sudden urinary incontinence.

Toviaz will be available as an extended-release, once-daily tablet in either 4-mg or 8-mg dosage strengths. The recommended starting dose is 4 mg. Toviaz is approved only for adults. Toviaz is not recommended in doses above 4 mg in patients with severely reduced kidney function or in patients taking medications such as ketoconazole (Nizoral, Janssen) that block the metabolism of the drug. Toviaz should not be used in patients with urinary or gastric retention; uncontrolled, narrow-angle glaucoma; or severe liver impairment.

(Source: FDA, November 4, 2008; www.pfizerpro.com.)

Rufinamide (Banzel) For Seizures Associated with Lennox–Gastaut Syndrome
The FDA has approved rufinamide (Banzel, Eisai) for the adjunctive treatment of seizures associated with Lennox–Gastaut syndrome (LGS) in adults and in children four years of age and older.

Children usually experience the onset of LGS between one and five years of age, and from 3% to 7% of these patients die within less than 10 years.

Rufinamide is a triazole derivative and is structurally unrelated to other anti-epileptic drugs. It is believed to exert its effect by regulating the activity of sodium channels in the brain. The drug’s effectiveness for this indication was established in a multicenter, double-blind, placebo-controlled, randomized study of 138 patients.

Antiepileptic drugs can increase the risk of suicidal thoughts or behavior in patients. Rufinamide has been associated with somnolence, coordination abnormalities, dizziness, gait disturbances, and ataxia. As with all antiepileptic agents, rufinamide should be gradually withdrawn to minimize the risk of increased seizure frequency.


Eltrombopag (Promacta) For Thrombocytopenia
An accelerated approval has been granted for GlaxoSmithKline’s eltrombopag (Promacta), the first oral thrombopoietin receptor agonist for treating thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have not responded adequately to corticosteroids, immunoglobulins, or splenectomy.

Chronic ITP is marked by increased platelet destruction or inadequate platelet production in the blood. Eltrombopag stimulates the proliferation and differentiation of megakaryocytes, the bone marrow cells that give rise to blood platelets.

The company is launching the Promacta Cares program. Prescribers and pharmacies must enroll in the program before they can prescribe or dispense eltrombopag, and patients are required to enroll before they can receive the drug.

(Source: GlaxoSmithKline, November 20, 2008.)

Generic Approvals

Generic Sarafem (Fluoxetine)
Mylan Pharmaceuticals, Inc., has received final approval from the FDA for Fluoxetine Capsules USP, 10 mg and 20 mg. The capsules, which are indicated for patients with premenstrual dysphoric disorder, are the generic version of Eli Lilly’s Sarafem Pulvules Capsules.

(Source: Mylan, November 18, 2008.)

Generic Pulmicort (Budesonide) For Asthma
Teva Pharmaceutical Industries Ltd. has announced the FDA’s approval of its Abbreviated New Drug Application (ANDA) to market a generic version of AstraZeneca’s Pulmicort (budesonide) Respules, 0.25 mg/2 mL and 0.5 mg/2 mL. Budesonide is indicated for the twice-daily treatment of asthma.

Shipment of the product began on November 18, just hours after approval; however, on November 20, a temporary order froze the supply to prevent future sales. Teva is involved in patent litigation concerning this product in the U.S. District Court in New Jersey. A patent trial
Drugs News is scheduled for January 12, 2009.
(Sources: Associated Press, November 21, 2008; Teva, November 19, 2008.)

**NEW INDICATIONS**

**Dexmedetomidine (Precedex) For Sedation**

Dexmedetomidine HCl (Precedex, Hospira) was originally approved for the sedation of intubated and mechanically ventilated patients in intensive-care units (ICUs) for up to 24 hours. The new approval is indicated for non-intubated patients needing sedation before or during surgery and was based on the results of two randomized studies: MAC (Monitored Anesthesia Care) and AWAKE.

This relatively selective alpha2-adrenoceptor agonist can be used before, during, and after extubation.

(Source: Hospira, October 30, 2008.)

**Growth Hormone (Norditropin) to Help Small-For-Gestational-Age Children**

Children who are born with a condition that can prevent them from growing to a normal height now have a treatment option with Norditropin (somatropin [rDNA origin] injection). The drug treats short stature in small-for-gestational-age children whose growth has not caught up by the time they are two to four years of age. In a 13-year trial, 63% of the treated children who reached adult height were in the normal range of their peers.

Each year, approximately 100,000 infants in the U.S. are born weighing less than 97% of all other babies of the same gestational age. These children may be at increased risk for obesity, insulin resistance, carbohydrate intolerance, dyslipidemia, and psychosocial disadvantages.

Norditropin injection is also indicated for children with short stature associated with Noonan syndrome, with short stature associated with Turner syndrome, and with growth failure from inadequate secretion of endogenous GH. This product is also indicated for replacing GH in adults with GH deficiency of adult onset or of childhood onset.

(Source: Novo Nordisk, November 4, 2008.)

**Insulin Glulisine (Apidra) For Diabetic Children**

Sanofi-Aventis has received approval of insulin glulisine [rDNA origin] injection (Apidra) to improve glycemic control in children and adolescents four years or older and who have diabetes mellitus.

The approval was based on the FDA’s review that compared insulin lispro (Humalog, Eli Lilly) in 572 children and adolescents with type-1 diabetes. No noteworthy differences existed between treated groups in the number of patients reporting hypoglycemia. Hypoglycemia occurred in 7.2% of the glulisine patients and in 8.1% of the lispro patients.

Insulin glulisine can be given by an infusion pump, a vial, a syringe, the OptiClik reusable insulin pen, or intravenously. This agent helps to lower glycosylated hemoglobin (HbA1c) levels in adults and in children four years of age and older with type-1 diabetes and in adults with type-2 diabetes.

(Source: Sanofi-Aventis, October 29, 2008.)

**NEW MEDICAL DEVICES**

**CLARO Acne-Clearing Device**

**Name:** CLARO Acne-Clearing Device

**Manufacturer:** CLRS Technology, Costa Mesa, Calif.

**Approval Date:** October 29, 2008

**Use Classification:** This is the first handheld apparatus to use intense pulsed light for patients with acne.

**Purpose:** A series of light pulses, delivered in six seconds, safely penetrates the skin to eliminate the bacteria that cause acne and to reduce inflammation. Clinical studies demonstrated a 94.8% decrease in Propionibacterium acnes bacteria after just one treatment.

**Benefit:** Pulsed light technology combines heat and light to clear acne rapidly.

**Sources:** www.pharmacyonesource.com; www.ikonisys.com/her2/her2_Brochure.pdf; J Oncol Practice, 2007;3(1): 48–50

**Name:** CLARO Acne-Clearing Device

**Manufacturer:** CLRS Technology, Costa Mesa, Calif.

**Approval Date:** October 29, 2008

**Use Classification:** This device is used to treat mild-to-moderate inflammatory acne.

**Description:** This is the first handheld apparatus to use intense pulsed light for patients with acne.

**Purpose:** A series of light pulses, delivered in six seconds, safely penetrates the skin to eliminate the bacteria that cause acne and to reduce inflammation. Clinical studies demonstrated a 94.8% decrease in Propionibacterium acnes bacteria after just one treatment.

**Benefit:** Pulsed light technology combines heat and light to clear acne rapidly.

**Sources:** www.pharmacyonesource.com; www.clrstechology.com; www.emaxhealth.com

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Name: Flair Endovascular Stent Graft  
Manufacturer: C. R. Bard Inc., Murry Hill, N.J.  
Approval Date: October 29, 2008  
Use Classification: This stent graft is indicated to treat stenosis in synthetic arteriovenous bypass grafts.  
Description: A self-expanding Nitinol stent is encapsulated within the ePTFE (Teflon) graft material. This model has been slightly modified from an older one that was approved in 2007.  
Purpose: The stent graft restores blood flow and keeps the area open.  
Benefit: This is the first interventional device to show superiority to balloon angioplasty for maintaining access patency. In a six-month study, placement of the stent graft resulted in more than twice the patency of balloon angioplasty.  

Future Anti-clotting Study  
Several competing manufacturers of drugs and medical devices plan to collaborate to find the best way to prevent potentially deadly blood clots from forming in heart patients who have received implanted arterial stents. Each year, from 800,000 to one million American patients need one or more stents to keep an artery open after it has been unblocked by angioplasty.  
The question centers on how long patients may need anticoagulant drugs. From 25,000 to 30,000 patients who have had one of the tiny metal-mesh tubes implanted in a heart artery will participate in the multicenter study. Enrollment will most likely begin in late 2008 or in early 2009.  
Most patients will receive drug-coated stents, which release medication over time, and at least 5,000 patients will be receiving the older bare-metal stents.  
Sources: www.pharmacyonesource.com; Associated Press WorldStream, October 16, 2008