NEW DRUGS

Prolia for Osteoporosis

The FDA has approved denosumab (Prolia, Amgen) for postmenopausal women with osteoporosis and a high risk of fracture. Denosumab is given every six months as a subcutaneous injection.

In a three-year phase 3 study, treatment resulted in greater bone density, stronger bones, and a reduced risk of vertebral, hip, and nonvertebral fractures at three years. Denosumab also resulted in significant suppression of bone remodeling; however, long-term suppression of bone remodeling may contribute to osteonecrosis of the jaw, atypical fractures, and delayed fracture healing.

Denosumab is contraindicated in patients with hypocalcemia. Patients should be taking adequate supplements of calcium and vitamin D. The company is including a Risk Evaluation and Mitigation Strategy (REMS) and a patient medication guide.

Sources: N Engl J Med 2009;361(8):756–765; Amgen, June 1, 2010

Jalyn Relieves Benign Prostatic Hyperplasia

GlaxoSmithKline has won approval for a fixed-dose combination (Jalyn) containing dutasteride and tamsulosin for men with benign prostatic hyperplasia (BPH). Dutasteride is made by GlaxoSmithKline as Avodart, and tamsulosin is the active ingredient in Flomax (Astellas Pharma). Approval was based on two-year results from a large study, COMBAT study (Combination of Avodart and Tamsulosin), of almost 4,900 patients.


NEW INDICATION

Tasigna in Early Leukemia

Nilotinib (Tasigna, Novartis) has been approved for adults with early-stage Philadelphia chromosome–positive chronic-phase chronic myeloid leukemia (Ph+CP-CML). This slowly progressing blood and bone marrow disease is linked to a genetic abnormality. Nilotinib is believed to block a signal that leads to leukemic cell development.

The FDA originally approved nilotinib in October 2007 for adults whose disease had progressed or who could not tolerate other therapies. A boxed warning mentions the risk of QT prolongation.

Source: June 17, 2010

DRUG NEWS

Ipilimumab Prolongs Survival in Melanoma Patients

An experimental drug has been found to improve survival in patients with advanced melanoma. Ipilimumab (Bristol-Myers Squibb/Medarex) helps the immune system attack tumors. The FDA has promised an accelerated review.

A study included 676 patients with inoperable melanoma who had already tried other treatments. They received ipilimumab alone, the drug plus another immune-stimulating treatment, or an immune-stimulating treatment alone. After two years, 24% of patients receiving ipilimumab alone or in combination were still living, compared with 14% of those receiving only the immune-stimulating treatment.

Average survival was 10 months with ipilimumab and a bit more than six months with the other therapies.


Labeling Revised For Some Asthma Drugs

Labels have been revised for both single-ingredient and combination long-acting beta-agonist (LABA) agents for patients with asthma. In February 2010, the FDA had announced that it would require manufacturers to revise their drug labels because of an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations and sometimes death in some patients using LABAs.

The boxed warning now states that single-ingredient LABAs increase the risk of asthma-related death. Approved LABAs include salmeterol (Serevent, GlaxoSmithKline), formoterol (Foradil Aerolizer, Schering), salmeterol/fluticasone (Advair, GlaxoSmithKline), and formoterol/budesonide (Symbicort, AstraZeneca).

The updates state that (1) patients should not use a LABA alone without a long-term asthma control medication, such as an inhaled corticosteroid (ICS), (2) they should not use a LABA if their asthma is controlled with a low-dose or medium-dose ICS, (3) they may use a LABA as an adjunctive therapy only if their asthma is not adequately controlled with a long-term control medication, (4) patients should be assessed regularly after asthma is controlled, and (5) children and adolescents who need the addition of a LABA to an ICS should use an...
ICS/LABA combination product.

Source: www.empr.com, June 3, 2010

Two FDA Initiatives Increase Safety Awareness

The FDA plans to collaborate with Drugs.com to provide FDA consumer updates, videos, and slide shows on the Drugs.com Web site. The partnership will also enable access to information on Drugs.com’s mobile phone platform.

The FDA also announced that it has begun to release quarterly risk summaries about medications approved after September 2007 and will be posting them on its Web site. On June 22, the agency released summaries for two vaccines and 24 drugs for hypertension, allergies, HIV infection, and other conditions.

Sources: FDA, May 26, 2010; Reuters, June 15, 2010; Drug Topics, June 23, 2010

Fake Tamiflu Is Dangerous In Penicillin Allergy

The FDA is warning consumers about a potentially harmful product represented as “generic Tamiflu,” sold over the Internet. This fraudulent product does not contain Tamiflu’s active ingredient, oseltamivir; it contains cloxacillin, an ingredient in the same class of antibiotics as penicillin. Patients who are allergic to or who have had an adverse reaction from penicillin products are at risk of experiencing a similar reaction from cloxacillin, such as anaphylaxis. There is no FDA-approved generic drug for the prescription product Tamiflu.

The FDA bought the fraudulent product without a prescription from a Web site claiming to be an online drugstore. Even though that site is no longer operational, the fraudulent version is likely to be found for sale on other Web sites. The product arrived in an envelope sent from India, containing two foil-backed blister packages each with 15 yellow and tan capsules containing white powder. The foil backing is printed, and labeled in part, “Oseltamivir Phosphate 75 mg. Capsules TM-FLU Capsules” and “Manufactured by: TRYDRUGS Pharmaceuticals PVT.LTD.”

Source: FDA, June 17, 2010

Low-Dose Rosiglitazone Plus Metformin May Cut Risk of Diabetes

Low doses of rosiglitazone (Avandia, GlaxoSmithKline), combined with metformin (Glucophage, Bristol-Myers Squibb), may be able to prevent diabetes without causing the usual adverse effects. In a new (albeit small) study of 207 patients with pre-diabetes, taking half a dose of rosiglitazone plus metformin reduced the risk of development into type-2 diabetes by two-thirds.

After four years, 14% of patients receiving the two drugs developed diabetes, compared with 39% of those receiving placebo. Rosiglitazone is a thiazolidinedione, which helps the body use insulin efficiently; however, common side effects from this drug class include fluid retention, heart failure, and the possibility of heart attacks. Metformin, an older drug, can cause an upset stomach.

In the study, patients with pre-diabetes receiving rosiglitazone/metformin did not experience weight gain, fluid retention, or gastrointestinal effects. The study has not lasted long enough (3.4 years) to determine whether rates of heart failure or heart attack would rise, although fluid retention can indicate the potential for heart effects.

Whether a low dose of rosiglitazone, a controversial drug, can reduce the incidence of diabetes is under debate. Steven Nissen, MD, an outspoken critic of rosiglitazone, said that delaying the onset of diabetes is not that useful if adverse cardiovascular events are increased. He saw no evidence that lower doses of rosiglitazone were safe; further, the population was at low risk to begin with. He called the suggestion that cardiovascular toxicity could be avoid by a smaller dose was “purely speculative.”

Baiju Shah, MD, of the Sunnybrook Health Sciences Centre in Toronto, added that no harm was evident but that rosiglitazone should not be exonerated. The study did not include higher doses of metformin or rosiglitazone, leaving it unclear whether a high dose of a single drug would have the same effect as the lower-dose combination.


Liver Injury with Orlistat

Orlistat (Xenical, Genentech; Alli, GlaxoSmithKline), a weight-loss medication, poses a risk of liver damage, according to the FDA. Although this event is rare, the risk has led the FDA to revise the drug’s label. So far, 13 cases of adverse reactions have been identified among approximately 40 million patients using Xenical and Alli; 12 of the cases were reported outside the U.S. A cause-and-effect relationship of severe liver injury with orlistat has not been established; however, individuals taking either drug should be informed about the signs and symptoms of liver injury, including itching, yellow eyes or skin, dark urine, loss of appetite, or light-colored stools.

Source: FDA, May 26, 2010

First Test for H1N1 Virus

The SimplexInfluenza A H1N1 test (Focus Diagnostics) has been approved to detect the presence of the 2009 H1N1 flu virus in patients with signs and symptoms of respiratory infection. Specimens are obtained from nasal swabs or nasal aspirates. A positive result indicates an infection with H1N1, although a negative result does not preclude the possibility of
infection. The test does not indicate the stage of infection. Until this approval, tests for the 2009 H1N1 influenza were available only through an emergency use authorization.

Source: FDA, May 24, 2010

**Support System Recalled**

On May 10, 2010, specific lots of the Aisys and Avance Anesthesia Systems, made by GE Healthcare, were recalled. These prescription devices provide general inhalation anesthesia and ventilation support to patients. The affected systems were distributed between October 9 and 29, 2009. The Class I recall was instituted because a specific lot of the control board wiring harnesses has a defect, which can cause the machine to unexpectedly shut down. If this occurs, ventilation, delivery of the anesthetic, and possibly patient monitoring could be terminated.

Source: FDA, May 13, 2010

**NEW MEDICAL DEVICES**

Marvin M. Goldenberg, PhD, RPh, MS

**Name:** Acuity Break-Away Lead Delivery System

**Manufacturer:** Boston Scientific, Natick, Mass.

**FDA Approval Date:** May 13, 2010

**Purpose:** The Acuity device is used with specialized defibrillators and pacemakers, both of which treat patients with heart failure.

**Description:** An integrated, break-away hemostasis valve is designed to minimize blood loss and allows for a streamlined implantation experience so that fewer steps and instruments are needed during surgery. The smallest inner catheter lead delivery system on the market enables physicians to deliver a 4 French lead. Seven outer and two inner guide catheter shapes are designed to accommodate various anatomic structures.

**Benefit:** The Acuity delivery system helps to simplify the implant experience. Physicians can use this system along with the company’s various left ventricular leads, which have a 97% implant success rate. Four designs provide several options for securing the lead to the heart. An electronic repositioning device provides six configurations for stimulating the left side of the heart even after implantation, potentially obviating the need for an additional surgical procedure.


**Name:** Freestyle Lite Glucose Test Strips

**Manufacturer:** Abbott, North Chicago, Ill.

**FDA Approval Date:** May 19, 2010

**Purpose:** Used with Freestyle Lite and Freestyle Freedom Lite meters, the test strips measure glucose without measuring other sugars that can create falsely high glucose concentrations, as with previous strips.

**Description:** The test strips use glucose dehydrogenase–flavin adenine dinucleotide (GDH–FAD), an enzyme that is not affected by common non-glucose sugars, such as maltose and galactose.

**Benefit:** The new strips should help to eliminate inaccurate results for patients who take other medications. The device is designed to minimize interference during testing and to reduce the number of error messages and wasted strips.

**Precautions:** The strips should not be used beyond the expiration date or if the box seal is broken or missing. They should be stored at room temperature below 86°F (30°C) and should not be refrigerated or frozen.

Sources: www.abbott.com; www.pharmacychoice.com/News/article.cfm?Article_ID=583245