PRODUCT UPDATE

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Tyrosine Kinase Inhibitor May Be Used to Treat Solid Tumors

Tykerb® (lapatinib ditosylate, GlaxoSmithKline, Research Triangle Park, NC) presently is receiving priority review from the U.S. Food and Drug Administration (FDA) for its promise as a combination therapy to treat solid tumor cancers. Tykerb currently is an investigational drug. Protein tyrosine kinases are enzymes present in cells that provide a central switch mechanism in cellular signal transduction pathways. They are involved in many cellular processes such as cell proliferation, metabolism, survival, and apoptosis. Tykerb is a small-molecule, dual-receptor tyrosine kinase inhibitor that blocks tyrosine kinase activity, thereby hindering cellular proliferation and potentially cancer cell growth. Some encouraging evidence suggests that Tykerb may have efficacy in inflammatory breast cancer, a highly aggressive form of breast cancer that has a particularly poor prognosis, and may be especially promising in combination with Herceptin® (trastuzumab, Genentech, Inc., South San Francisco, CA) to treat HER2-positive breast cancer.

Based on the available data, once-daily oral Tykerb appears generally well tolerated, with rash, fatigue, and diarrhea occurring as the most commonly reported treatment-related adverse events. For more information about Tykerb, visit www.gsk.com.

New Blood Pressure Drug Approved

The FDA has granted tentative approval to Novartis's (East Hanover, NJ) hypertension drug, Exforge®. Exforge is a new combination drug that joins two commonly prescribed hypertension medications—Diovan® (valsartan, Novartis) and Norvasc® (amlodipine besylate (Pfizer Inc., New York, NY)—in one tablet as a single, daily oral dose.

In clinical trials involving more than 5,000 patients, Exforge helped patients gain control of their blood pressure and reach their treatment goals. The drug is expected to be released in September 2007 pending the expiration of Norvasc's patent protection and market exclusivity. Exforge was approved based on improved efficacy and side effect profile compared to Norvasc alone. Exforge is indicated for the treatment of hypertension but not for initial therapy. The drug is recommended for patients whose blood pressure is not controlled adequately with any dihydropyridine calcium channel blocker or angiotensin receptor blocker. Also, the drug is appropriate for patients who experience dose-limiting side effects on either component, such as amlodipine-induced edema, dizziness, or flushing. Look for more information about Exforge later in the year.

Investigational Drug May Treat Idiopathic Thrombocytopenic Purpura

An investigational oral platelet growth factor increased platelet counts in patients with chronic idiopathic thrombocytopenic purpura (ITP). ITP is an autoimmune disorder marked by decreased platelet production and/or increased platelet clearance and bleeding from the small blood vessels. In multinational randomized, controlled trials, Promacta™ (eltrombopag, GlaxoSmithKline) increased platelet counts in patients with ITP.

GlaxoSmithKline announced additional information from a study of Promacta at the 48th Annual American Society of Hematology meeting in Orlando, FL, in December 2006. Analysis of data from the study showed that Promacta resulted in a positive trend toward decreased bleeding incidence (all grades) in adult patients with chronic ITP.

Promacta is an investigational nonpeptide thrombopoietin receptor agonist that has been shown in preclinical research and clinical trials to stimulate the proliferation and differentiation of megakaryocytes, the bone marrow cells that give rise to blood platelets. Promacta is administered orally as a tablet and may have less potential than large protein molecules for causing an immune system reaction. The safety profile will be examined further in the ongoing clinical trials program. Promacta is an investigational compound that has not received regulatory approval in any market for any indication at this time. Clinical trials of Promacta are continuing for use in ITP and other conditions where thrombocytopenia is of concern, such as chemotherapy use and liver disease. For more information, visit www.gsk.com.

Breast Cancer Drug Receives Expanded Approval

The FDA has expanded approval of Herceptin to include its use as adjuvant therapy in the treatment of early-stage HER2-positive breast cancer.

Herceptin, already approved for metastatic breast cancer, now also is indicated for women who have undergone lumpectomy or mastectomy for treatment of tumors confined to the breast or lymph nodes. The FDA has expanded the approved use of Herceptin to be used in combination with other cancer drugs for the treatment of HER2-positive breast cancer after surgery (lumpectomy or mastectomy).

Herceptin is a targeted therapy against the HER2 protein on cancer cells. Excessive amounts of HER2 protein cause cancer cells to grow more rapidly, and standard chemotherapy may be less effective. In 1998, the FDA approved Herceptin for the treatment of metastatic breast cancer, and the new approval expands its use to women with cancer in the breast and regional lymph nodes that have been removed surgically. Herceptin should be prescribed only for women diagnosed with HER2-positive breast cancer. For more information on the drug, visit www.herceptin.com.

New Antinausea Drug Acts on Endocannabinoid Receptors

Cesamet™ (nabilone, Valeant Pharmaceuticals, Costa Mesa, CA) is a new drug available to treat chemotherapy-induced nausea and vomiting in patients for which conventional treatments have failed. Cesamet is a synthetic cannabinoid that is thought to trigger its effects by activating the endocannabinoid receptors. The receptors are involved in regulating nausea and vomiting. Cesamet has a long duration of action, which allows for typically twice-daily oral dosing. For more information, visit www.cesamet.net.

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