PRODUCT UPDATE

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New Drug May Treat Rare Skin Cancer

A new drug has been approved to treat persistent, progressive, or recurrent advanced cutaneous T-cell lymphoma (CTCL), which affects approximately 20,000 Americans. The U.S. Food and Drug Administration (FDA) recently approved Zolinza® (vorinostat) (Merck & Co., Inc., Whitehouse Station, NJ), a once-daily oral capsule, for the treatment of CTCL, a non-Hodgkin lymphoma that manifests on the skin. Malignant T cells migrate to the skin, where they may be deposited. Vorinostat has been approved for patients who have failed other therapies and whose CTCL persists or worsens. Serious side effects of Zolinza included pulmonary embolism, dehydration, anemia, and deep vein thrombosis. Zolinza is in a new class of cancer drugs known as histone deacetylase (HDCA) inhibitors. The drug is believed to interfere with the enzymatic activity of HDCA and help stop or retard the growth of cancer cells, although the exact mechanism of Zolinza is unknown. The FDA approved Zolinza under its orphan drug program, which provides incentives for companies to develop treatments for rare diseases. For more information, visit www.zolinza.com.

Chemotherapy Drug Has Additional Indication for Lung Cancer

Avastin® (bevacizumab) (Genentech Inc., South San Francisco, CA) has received a new indication for use as a first-line treatment for non-small cell lung cancer when used in conjunction with carboplatin and paclitaxel. Along with the new indication, Genentech announced plans to cap the cost of Avastin (bevacizumab) at $55,000 annually for patients below a certain income threshold beginning in January 2007. Patients with lung cancer must take twice the amount of Avastin as those with colorectal cancer, doubling average monthly costs to nearly $8,800 and bringing annual costs to more than $100,000. Rather than limiting the relief to patients' out-of-pocket expenses, the $55,000 annual cap would apply to drug spending for eligible patients from all payers, including Medicare, private insurers, and patients. For more information, visit www.avastin.com.

Oral Agent Is Part of a Novel Class of Diabetes Therapies

The FDA has approved Januvia® (sitagliptin phosphate, Merck & Co., Inc.) for type 2 diabetes, the first in a new class of diabetes therapies. Januvia is a dipeptidyl peptidase-4 (DPP-4) inhibitor that raises levels of a naturally occurring protein that stimulates the pancreas to produce insulin. The drug takes effect only when patients are hyperglycemic already, reducing the risk of hypoglycemia. The novel mechanism of Januvia is glucose dependent, responding to the presence of elevated glucose and resulting in the release of insulin and decrease of glucagon only when needed. By inhibiting the DPP-4 enzyme, Januvia significantly raises the levels of active incretin hormones, increasing the synthesis and release of insulin from pancreatic beta cells and decreasing the release of glucagon from pancreatic alpha cells. Januvia can be used alone as a single-drug therapy or in conjunction with other oral agents. Additionally, the once-daily pill might prove more convenient than competing injection-based therapies. The most common side effects reported with Januvia were nasal congestion and sore throat, upper-respiratory infection, and headache. For more information, visit www.januvia.com.

Monoclonal Antibody Will Treat Colorectal Cancer

A new monoclonal antibody, Vectibix® (panitumumab) (Amgen Inc., Thousand Oaks, CA), has been approved by the FDA. Vectibix targets the epidermal growth factor receptor and is indicated for patients who have metastatic colorectal cancer after standard, first-line therapy. Vectibix has shown increased time to disease progression, and some patients have shown tumor shrinkage. Side effects include pulmonary fibrosis, severe skin rash, infusion reactions, and fatigue. Drugs approved under the accelerated approval program run by the FDA must continue to be monitored, and postmarketing studies still must be conducted to show whether the drug improves the survival of patients with fewer prior chemotherapies. For more information, visit www.vectibix.com.

Antifungal Agent Prevents Infections in Immunosuppressed Patients

The FDA has approved Noxafil® (posaconazole) (Schering-Plough, Kenilworth, NJ) to prevent invasive *aspergillus* and *candida* infections in immunosuppressed patients.

Noxafil, a triazole antifungal with an active substance that has never before been approved for marketing in any form in the United States, could be used for patients who have undergone bone marrow transplants or are having chemotherapy. It is a cherry-flavored, immediate-release suspension agent. Noxafil must be taken with a full meal or nutritional supplement to be absorbed adequately into the body. The most common side effects in patients treated with Noxafil were nausea, vomiting, diarrhea, rash, decreased potassium blood levels and platelet counts, and abnormalities in liver function tests. Noxafil has been shown to interact with several medications, including drugs that suppress the immune system, and the reactions may be serious. The product label should be consulted when other drugs are prescribed with Noxafil. For full prescribing information, visit www.noxafil.com.

Oral Chemotherapy Drug Is Approved for Several New Indications

The FDA has approved imatinib mesylate (Gleevec®, Novartis Pharmaceuticals, East Hanover, NJ) as a single agent for the treatment of dermatofibrosarcoma protuberans, myelodysplastic or myeloproliferative diseases, aggressive systemic mastocytosis, hypereosinophilic syndrome or chronic eosinophilic leukemia, and relapsed or refractory Philadelphia chromosome–positive acute lymphocytic leukemia. For full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications, visit www.fda.gov/cder/foi/label/2006/021588s011-s012-s013-s014-s017lbl.pdf.

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