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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NEW PRODUCTS

Nasogastric Tube Holder Is Patient Friendly

Dale Medical Products, Inc. (Plainville, MA), has introduced individually packaged nasogastric tube holders that stay in place to stabilize tube movement and prevent nasal irritation, erosion, and necrosis for as long as three days. The Dale® NasoGastric Tube Holder is a latex-free nose pad that stretches and conforms to a patient's nose, regardless of size or shape, and has a skin-friendly adhesive that resists humidification. Featuring dual tabs that spiral wrap around the tube in opposite directions to hold it securely and prevent nasal irritation, erosion, and necrosis, the nasogastric tube holder is easy to apply and can remain in place for as long as three days. For more information, visit www.dalemed.com.

New Device Makes Sputum Collection Easier

Medical Acoustics LLC (Buffalo, NY) announced that its new device, the Lung Flute®, has been cleared by the FDA for sputum induction for diagnostic purposes. The simple, handheld, disposable device supplements a patient's natural mucus-clearing system by introducing low-frequency sound waves into the lungs. The Lung Flute is a novel medical device that will be helpful for patients with asthma, chronic bronchitis, community-acquired pneumonia, and lung cancer. Deep lung secretions can be obtained to determine drug efficacy and progression of treatment for pulmonary drugs. Currently, sputum induction using hypertonic saline is the standard method, but such samples cannot be collected frequently. The Lung Flute will allow sputum samples to be collected every 20 minutes, which is important when monitoring inflammatory markers during asthma attacks. Visit www.medicalacoustics.com for more information.

RECALLS AND ALERTS

Defective Test Strips Are Recalled

Roche Diagnostics (Indianapolis, IN) and the FDA have instituted a recall of CoaguChek® PT test strips used to determine blood clotting time of patients taking anticoagulant medication to prevent blood clots. The strips may indicate a falsely elevated result, which may cause patients to take an incorrect dose of anticoagulant medication or unnecessary corrective measures to reduce the effect of circulating anticoagulants.

Healthcare professionals who use CoaguChek PT test strips should institute duplicate testing or use two strips with different lot numbers on each patient to reduce the risk of error. Home users of CoaguChek PT test strips should immediately discontinue using the product and contact their healthcare providers. U.S. customers with questions or concerns and healthcare professionals with general questions should call Roche Diagnostics' Point-of-Care Technical Service at 800-820-0995.

Cardiac Warning Is Added to Chemotherapy Drug Package Insert

Novartis Pharmaceuticals and the FDA have announced that Novartis is making revisions to the prescribing section of the package insert for Gleevec (imatinib). Postmarketing data indicate that patients taking the drug may be at an increased risk for congestive heart failure, and the packaging label has been updated to include this information. Patients with preexisting comorbidities are at highest risk. Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully, and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Healthcare professionals should continue to report all serious adverse events suspected to be associated with the use of Gleevec to 888-669-6682.

Chemotherapy Drug May Cause Rare Neurologic Disorder

Genentech Inc. and the FDA notified healthcare professionals about revisions to the "Warnings" and "Adverse Events" sections of the prescribing information of Avastin (bevacizumab) to inform healthcare professionals of cases of (a) a rare brain-capillary leak syndrome (reversible posterior leukoencephalopathy syndrome [RPLS]) and (b) postmarketing reports of nasal septum perforation.

RPLS is a neurologic disorder associated with hypertension, fluid retention, and cytotoxic effects of immunosuppressive drugs on the vascular endothelium (lining of the blood vessels). The syndrome can present with headache, seizure, lethargy, confusion, blindness, and other visual and neurologic disturbances. Mild to severe hypertension may be present but is not necessary for diagnosis. The onset of symptoms has been reported to occur from 16 hours to one year after initiation of Avastin. In patients developing RPLS, discontinue Avastin and initiate treatment of hypertension if it is present. Symptoms usually resolve or improve within days, although some patients have experienced ongoing neurologic sequelae. Magnetic resonance imaging is necessary to confirm the diagnosis of RPLS. More information is available at www.avastin.com.

Drug Label Revised to Include Black Box Warning

The FDA and Bristol-Myers Squibb (New York, NY) have notified pharmacists and physicians of revisions to the labeling for Coumadin® (warfarin sodium) to include a new patient medication guide as well as reorganization and highlighting of the current safety information to better inform providers and patients. Bristol-Myers Squibb has added a black box warning to the Coumadin label that highlights the risk of major or fatal bleeding. The previous label warned of hemorrhage risk but did not include a black box, the most serious warning possible under FDA guidelines.

FDA regulation requires that a medication guide be provided with each prescription dispensed for products that the FDA determines pose a serious and significant public health concern, where one or more of the following circumstances exist: patient labeling could help prevent serious adverse effects; the drug product has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product; or the drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

To view the new medication guide, visit www.fda.gov/cder/Offices/ODS/MG/warfarinMG.pdf.

NOTEWORTHY

Women With Alopecia Have an Alternative to Wigs

Goddess Beauty, LLC, a female-owned company in San Francisco, CA, has developed a new method of hair extension application that allows women with medical conditions such as cancer to stop wearing wigs and instead use a secure, nondamaging, natural product.

The Goddess Hair™ Integration System uses premium-quality cuticle human hair matched exactly to a patient's own, takes an afternoon for a qualified hair extensionist to apply, and is a fraction of the cost of major hair replacement methods.

"We are excited to have come up with the Goddess Integration System. In support of our clients and their journeys, we also donate 10% of each hair integration appointment to the hair loss–associated charity of our client's choice," said Sheila Matechuck, designer of the hair extension system. For more information, visit www.goddessextensions.com/integrate.html.