PRODUCT UPDATE

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Leukemia Drug Receives Approval

Pegaspargase (Oncaspar®, Enzon Pharmaceuticals, Inc., Bridgewater, NJ) has received expanded approval from the U.S. Food and Drug Administration (FDA) for the treatment of newly diagnosed acute lymphoblastic leukemia. Previously, Oncaspar was approved only if patients could not receive L-asparaginase because of allergic reaction. Oncaspar is a modified version of L-asparaginase, and because of the modification, fewer allergic reactions are seen. Another benefit of Oncaspar over L-asparaginase is that it reduces the number of injections necessary during the course of treatment. Reported side effects of Oncaspar are anaphylaxis, pancreatitis, glucose intolerance, and bleeding problems.

Oncaspar will be one of the first drugs to be released with the new prescribing format designed by the FDA. The FDA unveiled a major revision to the format of prescription drug information (the package insert) to give healthcare professionals clear and concise prescribing information. In an effort to manage the risks of medication use and reduce medical errors, the newly designed package insert will provide the most up-to-date and easy-to-read content that draws physician and patient attention to the most important pieces of drug information before a product is prescribed. The new format also will make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Leukemia Drug Linked to Heart Failure

A study has found that Gleevec® (imatinib) (Novartis Pharmaceuticals, East Hanover, NJ) has been linked to serious cardiotoxicity with congestive heart failure. Gleevec is a tyrosine kinase inhibitor and is considered a targeted therapy, one of the first drugs to work specifically against cancer cells only and their underlying genetic problems. Gleevec works at the cellular level against the protein Bcr-Abl, which causes chronic myelogenous leukemia (CML). The drug treats CML and gastrointestinal stromal tumors. Studies have shown that the Abl tyrosine kinase protects cardiac cells from damage, and without it, heart cells die. Patients have developed congestive heart failure when they have had no evidence of heart disease prior to staring therapy. In clinical trials of Gleevec, severe peripheral edema and dyspnea were reported. The researchers recommended that patients taking Gleevec be followed closely for signs of heart failure.

New Combination Drug Will Treat Ovarian Cancer

Eli Lilly and Company (Indianapolis, IN) announced that the FDA has approved gemcitabine (Gemzar®) in combination with carboplatin for treatment of recurrent ovarian cancer. Clinical trials have shown that the combination therapy had a significantly higher response rate than the standard monotherapy of carboplatin. The combined therapy most commonly reported side effects of neutropenia and pancytopenia.

Oral Drug Approved for Multiple Myeloma

The FDA granted approval to lenalidomide oral capsules (Revlimid®, Celgene Corporation, Summit, NJ) for use in combination with dexamethasone in patients with multiple myeloma who have received one prior therapy. Revlimid is available under a special restricted distribution program, called RevAssist℠, which helps protect against fetal exposure to the drug.

Multiple myeloma is a cancer of the bone marrow in which white blood cells, called plasma cells, normally responsible for the production of antibodies (proteins that fight infection and disease), are overproduced. The proliferation of these abnormal plasma cells, known as myeloma cells, causes decreased production of normal red and white blood cells and normal disease-fighting antibodies, and it increases the growth of tumors that spread to multiple sites—hence the term multiple myeloma. The decreased white blood cell production damages the immune system, and myeloma tumors cause bone destruction that manifests as pain and fractures. Information about Revlimid and the RevAssist program can be obtained by calling the Celgene Customer Care Center at 888-423-5436 (toll-free phone).

Tamoxifen Is Now Available in Liquid Form

Cytogen Corporation (Princeton, NJ) announced that Soltamox™ (tamoxifen citrate, oral solution 10 mg/5 ml), the first liquid form of the hormonal breast cancer therapy tamoxifen, is now available in U.S. pharmacies. Soltamox received FDA marketing approval in October 2005 and is indicated for the treatment of metastatic breast cancer and to reduce the incidence of breast cancer in women who are at high risk for the disease.

Once-Daily Tablet Provides Easier Dosing for HIV Drugs

The FDA, through its fast-track program, has approved a once-daily tablet called Atripla™ (Bristol-Myers Squibb, Princeton, NJ, and Gilead Sciences, Inc., Foster City, CA) for HIV, a regimen that could simplify drug regimes for patients with HIV.

Each Atripla pill contains 600 mg of Sustiva® (efavirenz, Bristol-Myers Squibb), 200 mg of Emtriva® (emtricitabine, Gilead Sciences, Inc.), and 300 mg of Viread® (tenofovir DF, Gilead Sciences, Inc.), which are three of the most commonly used anti-HIV medications. The drug companies worked cooperatively to produce the new, once-daily pill. Atripla was approved on the basis of the original approvals for the three components, as well as a clinical trial. The development of single-pill, once-daily dosing has long been a goal of HIV researchers because taking antiretroviral medication faithfully is a key factor in keeping the virus in check. Some of the early regimens of highly active antiretroviral therapy required that patients take dozens of different pills, many times a day, either with food or without. Clearly, once-daily dosing is a desirable regimen.

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The 25th anniversary of the start of the AIDS epidemic occurred in 2006. The first cases of HIV/AIDS were reported by the Centers for Disease Control and Prevention (CDC) in the June 5, 1981, issue of the *Morbidity and Mortality Weekly Report.* The CDC currently estimates that more than one million Americans are infected with HIV, the virus that causes AIDS.

New Drug Helps Smokers Quit and Avoid Relapses

The novel antismoking prescription drug Chantix™ (varenicline, Pfizer Inc., New York, NY) is effective at helping people stop smoking and keep off cigarettes, according to several investigations. Three studies have shown that Chantix is more effective than placebo in helping patients stop smoking and in preventing smokers who have quit from relapsing. The studies may be somewhat limited but show that another product is available to help increase the probability of smoking cessation. Chantix is an oral tablet that is initially dosed once daily and is titrated up to a full dose twice daily. Nausea and insomnia are side effects of Chantix and usually resolve as treatment progresses. Treatment begins one week before the cessation of smoking and is recommended to continue for 12 weeks. Because smoking is the number-one preventable cause of lung cancer and heart disease, this new drug is of interest to cancer clinicians. For more information visit www.chantix.com.

NEW PRODUCTS

Video Game Helps Kids Fight Cancer

Re-Mission™ (HopeLab, Palo Alto, CA) is a computer-based video game rated "T" (for teen) and is available though Re-Mission.net. Re-Mission.net also serves as an interactive, online community for teens and young adults, who often are isolated as a result of their disease. The site is designed to allow teens with cancer to connect with each other and share information.

HopeLab conducted a randomized, controlled trial to test the effect of Re-Mission on treatment adherence, cancer-related knowledge, self-efficacy, and quality of life among adolescents and young adults with cancer. Results indicate that playing Re-Mission produced significant increases in quality of life, self-efficacy, and cancer-related knowledge for adolescents and young adults with cancer. In addition, young people who played Re-Mission maintained higher blood levels of chemotherapy and showed higher rates of antibiotic use than those in the control group, suggesting that Re-Mission helps patients adhere to cancer therapy regimens. The game, which is available in English, French, and Spanish, is free of charge to teens and young people living with cancer and is available to others at a suggested donation of $20.

Re-Mission is designed by HopeLab, which was founded in 2001. HopeLab is a nonprofit organization that combines rigorous research with innovative solutions to improve the health and quality of life of young people with chronic illness. This groundbreaking video game for teens and young adults with cancer is the product of a unique collaboration of researchers, leading video game developers and animators, cancer experts, cell biologists, psychologists, and young people with cancer. For more information on HopeLab, visit www.HopeLab.org.

Three New Automatic Pacemakers Are Approved

Medtronic, Inc. (Minneapolis, MN), announced that it has received FDA approval to begin marketing three fully automatic pacemakers that reduce unnecessary ventricular pacing when the heart is functioning normally. The Medtronic Adapta™, Versa™, and Sensia™ pacemaker models also offer an array of automatic features to improve pacing therapy. The systems provide physiologic pacing adapted to the needs of individual patients, helping to set new standards of care that reduce unnecessary pacing when the heart's natural conduction is present. For more information on the new technologies, visit www.medtronic.com.

PRODUCT ALERTS

Home Genetics Test Is Not Approved

The FDA, Federal Trade Commission, and CDC alerted consumers about the facts surrounding the direct-to-consumer marketing of genetic tests.

According to the FDA, which regulates the manufacturers of genetic tests, and the CDC, which promotes health and quality of life, some of the tests lack scientific validity and others provide medical results that are meaningful only in the context of a full medical evaluation. The FDA and CDC say that because of the complexities involved in the testing and interpretation of the results, genetic tests should be performed in specialized laboratories and the results should be interpreted by doctors or trained counselors who understand the value of genetic testing for a particular situation.

For additional information on the public notice, see the entire message at www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.htm.

To find out whether an over-the-counter genetic test is approved or cleared by the FDA, search the Over-the-Counter Tests Database at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm.

Gadolinium May Affect Patients With Kidney Failure

The FDA notified healthcare professionals and consumers that it is evaluating important safety information about gadolinium-containing contrast agents and a disease known as nephrogenic systemic fibrosis or nephrogenic fibrosing dermopathy (NSF/NFD) that occurs in patients with kidney failure. The disease manifests on the skin and appears as large areas of hardened skin with slightly raised plaques, papules, or confluent papules. New reports have identified a possible link between NSF/NFD and exposure to gadolinium-containing contrast agents used at high doses for magnetic resonance angiography (MRA). The FDA has learned of 25 cases of NSF/NFD in patients with kidney failure who received Omniscan™ (GE Healthcare, Chalfont St. Giles, United Kingdom), a gadolinium-containing contrast agent, and took the MRA test.

The FDA is gathering additional information about NSF/NFD and actively is investigating whether exposure to a gadolinium-contrast agent for MRA is associated with the development of NSF/NFD and whether other patients who received gadolinium-containing contrast agents developed NSF/NFD. The FDA has not yet determined whether exposure to these products during an MRA test causes NSF/NFD in patients with kidney failure. The FDA urges healthcare providers and patients to report adverse event information to the FDA online at www.fda.gov/medwatch/report.htm, by phone (800-FDA-1088), or by fax (800-FDA-0178).

Practitioners Should Be Aware of Risks With Promethazine

Promethazine injection is a commonly used drug for its antihistamine, sedative, anti–motion sickness, and antiemetic effects. The drug is also a known vesicant that is highly caustic to blood vessels and surrounding tissue. Promethazine is compounded with phenol and has a pH from 4–5.5. Although deep injection into a large muscle is the preferred route of administration, product labeling states that the drug may be given by slow IV push. However, because of the frequency of severe, tragic, local injuries after infiltration or inadvertent intra-arterial injection, the Institute for Safe Medicine Practice recommends that the FDA reexamine the product labeling and consider eliminating the IV route of administration.

Severe tissue damage can occur regardless of the route of parenteral administration, although IV and inadvertent intra-arterial or

subcutaneous administration result in more significant complications, including burning, erythema, pain, swelling, severe spasm of vessels, thrombophlebitis, venous thrombosis, phlebitis, nerve damage, paralysis, abscess, tissue necrosis, and gangrene. Practitioners should be aware of the potential harm and cautiously monitor any IV administration of promethazine. Safety recommendations include limiting concentrations available and diluting the drug to enable administration over 15–20 minutes.

NOTEWORTHY

Panel Says Cervical Cancer Vaccine Should Be Routine for Girls Aged 11–12

A vaccine against cervical cancer should be added to the list of recommended routine shots for girls aged 11–12, a federal public health panel has urged.

The CDC's Advisory Committee on Immunization Practices agreed that the Gardasil® vaccine (quadrivalent human papilloma virus [HPV] types 6, 11, 16, 18, recombinant vaccine, Merck & Co., Inc., Whitehouse Station, NJ) against human HPV—the sexually transmitted disease that causes most cervical cancers—should be a routine part of care for American girls aged 11–12. The CDC also recommended that girls as young as nine could be vaccinated if parents and healthcare providers agree. Access to the vaccine should be given to females aged 13–26 to catch up, and the vaccine should be a part of the Federal Vaccines for Children Program, which provides free vaccines for children who are uninsured or are Medicaid recipients.

The vaccine targets four strains of HPV, including the two that are thought to be responsible for 70% of all cervical cancers. The vaccine has been found to be protective against vaginal and vulvar lesions associated with HPV as well. For more information, visit www.gardasil.com.

Web Site Identifies Clinical Trials

To increase the accessibility of information on hundreds of ongoing U.S. clinical trials, a Massachusetts-based patient information group has launched a Web site intended to serve as the "Google™ of clinical trial registries," identifying ongoing trials in a specific zip code or distance from patients' homes. The not-for-profit Center for Information and Study on Clinical Research Participation (Dedham, MA) used donated software to create www.searchclinicaltrials.org, a complimentary site that will link to more than 50 trial registries.

Heart Association Releases New Diet and Lifestyle Recommendations

The American Heart Association released new dietary and lifestyle guidelines that recommend limiting saturated and trans fatty acids in the diet, getting adequate physical activity, and avoiding exposure to tobacco products. Instead of counting calories or grams of fat, the association suggested that people choose foods that naturally limit their intake of such fats, prepare foods with healthier oils, and exercise portion control at all times. The guidelines call for limiting consumption of food and beverages with added sugars and eating a diet rich in fruits, vegetables, and whole grains. The lifestyle recommendations emphasize physical activity, weight control, avoidance of tobacco products, and achieving and maintaining healthy cholesterol, blood glucose, and blood pressure levels. To view the complete guidelines, visit www.americanheart.org.