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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