PRODUCT UPDATE

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Public Health Advisory Issued Concerning Nonsteroidal Anti-Inflammatory Drugs

The U.S. Food and Drug Administration (FDA) issued a public health advisory summarizing the agency's current recommendations about nonsteroidal anti-inflammatory drugs (NSAIDs). A public health advisory is a temporary measure while the FDA continues to review the data. The FDA has made the following recommendations.

- "Physicians prescribing Celebrex® (celecoxib) [Pfizer Inc., New York, NY] or Bextra® (valdecoxib) [Pfizer Inc.] should consider this emerging information when weighing the benefits against risks for individual patients. Patients who are at high risk of gastrointestinal bleeding, have a history of intolerance to nonselective NSAIDs, or are not doing well on nonselective NSAIDs may be appropriate candidates for cyclooxygenase-2 selective agents.
- Individual patient risk for cardiovascular events and other risks commonly associated with NSAIDs should be taken into account for each prescribing situation.
- Consumers are advised that all over-the-counter (OTC) pain medications, including NSAIDs, should be used in strict accordance with the label directions. If use of an OTC NSAID is needed for longer than 10 days, a physician should be consulted."

Additional information can be found at www.fda.gov/cder/drug/analgesics/default.htm. The FDA encourages healthcare providers and patients to report adverse drug events to the FDA through the MedWatch program by phone (800-FDA-1088) or fax (800-FDA-0178) or online at www.fda.gov/medwatch/index.html.

Gefitinib Found Not to Improve Survival for Non-Small Cell Lung Cancer

Gefitinib (Iressa®, AstraZeneca Pharmaceuticals, Wilmington, DE) was approved by the FDA in March 2003 through an accelerated approval program. The approval was based on a surrogate end point, a 10% response rate in this case, that was considered reasonably likely to increase survival. The accelerated approval was conditional on continued research that would actually demonstrate increased survival. However, gefitinib failed to demonstrate a significant survival advantage over patients receiving a placebo in a large clinical trial that included more than 1,000 patients. The sponsoring company, AstraZeneca, has stopped marketing the drug but will continue to make it available to patients who appear to benefit from it. The company will continue to analyze the data. Physicians are reminded that docetaxel (Taxotere®, Aventis, Bridgewater, NJ) and erlotinib (Tarceva®, OSI Pharmaceuticals, Melville, NY) have received approval for this indication and that pemetrexed (Alimta®, Eli Lilly and Company, Indianapolis, IN) has received accelerated approval. After further review of the study results, the FDA will determine whether gefitinib should be withdrawn from the market or if other regulatory actions are appropriate.

Erlotinib Approved for Advanced Non-Small Cell Lung Cancer

The FDA has announced approval of erlotinib (Tarceva) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer and who have failed at least one other prior chemotherapy regimen. Erlotinib inhibits epidermal growth factor receptor tyrosine kinase. It is an oral medication taken once daily until disease progression or unacceptable side effects occur. The most common side effects are rash and diarrhea. Reports of interstitial lung disease have been rare but occasionally fatal.

Results of a randomized, placebo-controlled, double-blind study were that patients in the erlotinib arm had a median survival of 6.7 months compared to 4.7 months in the placebo arm; at one year, 31.2% of patients in the erlotinib arm were alive compared to 21.5% in the placebo arm. For more information, visit www.gene.com or call 877-TARCEVA.

Palifermin Approved for Prevention and Treatment of Mucositis

Mucositis can be a painful and debilitating side effect of chemotherapy. Amgen Inc. announced that the FDA has approved palifermin (Kepivance™, Amgen Inc., Thousand Oaks, CA) for the prevention and treatment of mucositis in patients with hematologic cancers undergoing high-dose-rate chemotherapy with or without radiation therapy followed by bone marrow transplantation.

Palifermin is a recombinant human keratinocyte growth factor. It stimulates the growth and development of new epithelial cells to build up the mucosa. Palifermin is administered via IV for three consecutive days immediately before chemotherapy or radiation therapy and again for three consecutive days after bone marrow transplantation. The most common side effects were rash, pruritus, erythema, paresthesia, mouth or tongue disorders, and taste alterations. These side effects were transient and mild to moderate in severity. The most common serious adverse effect was skin rash. Currently, palifermin is not approved for use in solid tumors or in treatments that do not include bone marrow transplantantation. For more information, visit www.amgen.com or www.fda.gov/cder/drug/infopage/palifermin/paliferminQA.htm. To receive the full prescribing information via fax, call 800-772-6436.

Caspofungin Acetate Receives Expanded Indication

Merck & Co., Inc., in Whitehouse Station, NJ, has announced that the FDA has approved expanded indications for caspofungin acetate (Cancidas®). Caspofungin now may be used empirically to treat presumed fungal infections in patients with febrile neutropenia. The mechanism of action of caspofungin is to inhibit fungal cell wall synthesis of β (1,3)-D-glucan, an essential component of fungal cell walls. Caspofungin is administered via IV. The most commonly occurring side effects of caspofungin are fever, chills, rash, headache, hypokalemia, vomiting, and nausea. Hepatic abnormalities have been seen in healthy volunteers as well as patients receiving caspofungin. Full prescribing information should be reviewed prior to administering this drug. Several drug interactions are possible. For more information, visit www.merck.com.

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