PRODUCT UPDATE

Vickie K. Fieler, RN, MS, AOCN®
Associate Editor

PHARMACY CORNER

Azacitidine Approved for Myelodysplastic Syndrome

Azacitidine (Vidaza™, Pharmion, Boulder, CO) was approved by the U.S. Food and Drug Administration (FDA) for all subtypes of myelodysplastic syndromes. The approval came less than five months after Pharmion submitted its new drug application. Azacitidine previously had been approved for fast-track and orphan drug status. Myelodysplasia has five subtypes, and the FDA called azacitidine the first effective treatment for this disorder.

Azacitidine is believed to cause hypomethylation of DNA and direct cytotoxicity on abnormal hematopoetic cells in bone marrow. Azacitidine causes the death of all rapidly growing cells but has little effect on nonproliferating cells. It is excreted primarily via the kidneys.

Azacitidine may cause fetal harm and should not be given to pregnant women. Men should not father a child while receiving azacitidine. Common adverse reactions to the drug include nausea, anemia, thrombocytopenia, vomiting, fever, leukopenia, diarrhea, fatigue, erythema at the injection site, constipation, neutropenia, and ecchymosis. Infrequent but dose-limiting adverse reactions include leukopenia, thrombocytopenia, neutropenia, and fever.

The treatment regimen for azacitidine usually is 75–100 mg/m^2 subcutaneously administered daily for seven days every four weeks. Known hypersensitivity to azacitidine or mannitol is a contraindication, as is advanced malignant hepatic disease. See full prescribing information for more information. Reimbursement and financial assistance programs are available. For more information, call 866-PHARMION or visit www.vidaza.com.

New Indication Approved for Gemcitabine

The U.S. Food and Drug Administration has approved gemcitabine, in combination with paclitaxel, for first-line treatment of metastatic breast cancer. Other approved indications for gemcitabine include treatment of metastatic pancreatic cancer and use with cisplatin for the treatment of advanced non-small cell lung cancer. Phase III studies showed that gemcitabine with paclitaxel was more effective than paclitaxel alone and had manageable side effects. Patients who received the combination drugs experienced higher rates of alopecia, neutropenia, and fatigue. For more information, call 888-443-6927 or visit www.lillyoncology.com.

Atrasentan Will Be Submitted for New Drug Application

Abbott Laboratories in Abbott Park, IL, announced it will submit atrasentan (Xinlay™) for a new drug application (NDA) by the end of 2004. The drug has been granted fast-track status from the U.S. Food and Drug Administration. The NDA is based on a meta-analysis of two phase III clinical trials. Individually, each clinical trial did not show statistical significance but did show trends in favor of treatment with atrasentan. Combined, the meta-analysis demonstrates statistically significant outcomes for atrasentan over placebo.

Atrasentan is an oral, once-a-day, nonhormone, nonchemotherapy, anticancer agent. It belongs to a new class of drugs know as selective endothelin-A receptor antagonists, which antagonize the effect of one of the proteins thought to be involved in metastasis. So far, atrasentan has been studied in men with metastatic, hormone-refractory prostate cancer. It is being used in a phase III trial of men with hormone-refractory prostate cancer that is not metastatic. Researchers also are using atrasentan with other cancers such as kidney, brain, ovarian, and non-small cell lung cancer.

The most common adverse effects of atrasentan are headache, peripheral edema, and rhinitis. For more information, visit www.abbott.com.

Advisory Committee Recommends Approval of Pemetrexed

The Oncologic Drugs Advisory Committee has recommended that the U.S. Food and Drug Administration approve pemetrexed (Alimta®, Eli Lilly & Co., Indianapolis, IN) for second-line treatment of non-small cell lung cancer. Pemetrexed already is approved for the treatment of mesothelioma in conjunction with cisplatin. The committee based its recommendation on a phase III trial that found pemetrexed had similar survival and response rates to the standard treatment with docetaxel but less severe side effects. For more information, visit www.lilly.com.

Therion Biologics Will Start Phase III Trial With a Vaccine for Treatment of Advanced Pancreatic Cancer

Therion Biologics in Cambridge, MA, announced the initiation of a pivotal clinical trial using PANVAC™-VF, a vaccine developed for the treatment of metastatic pancreatic cancer in patients who failed gemcitabine treatment. The study will enroll 250 patients, and its endpoint will be overall survival compared to palliative chemotherapy or best supportive care. This study will be conducted under a special protocol assessment. In earlier phase I trials, patients treated with the vaccine had increased survival compared to historical controls.

PANVAC-VF is designed to stimulate the immune system and destroy cancer cells that express carcinoembryonic antigen (CEA) and mucin-1. These proteins can be found on more than 90% of pancreatic tumor cells. The vaccine also contains Tricom™, a triad of costimulatory molecules that enhance and sustain an immune response against tumor cells. Treatment includes an initial priming dose followed by booster vaccinations.

Therion Biologics also is planning clinical trials in other types of cancers that are known to express CEA and mucin-1. For more information, visit www.therionbio.com.

Bedford Laboratories to Market Prochlorperazine

The U.S. Food and Drug Administration has given Bedford Laboratories in Bedford, OH, approval to market prochlorperazine edisylate injection USP. This is a generic brand of Compazine® (GlaxoSmithKline, Research Triangle Park, NC) that is indicated for the treatment of severe nausea and vomiting. In recent months, many areas of the country have had prochlorperazine in short supply. Having the generic brand available should help to ease the shortages. For full prescribing information, call 800-521-5169 or visit www.bedfordlabs.com.

Drug Warning Issued for Bevacizumab

Genentech, Inc., in South San Francisco, CA, issued a warning advising practitioners of a serious adverse event that has been associated with bevacizumab (Avastin™). "There is evidence of an increased risk of serious arterial thromboembolic events including cerebrovascular accidents, myocardial infarctions, transient ischemic attacks, and angina, related

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