PRODUCT UPDATE

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PHARMACY CORNER

U.S. Food and Drug Administration Expands Pegfilgrastim Indication to Now Treat Moderate Neutropenia

Amgen Inc. in Thousand Oaks, CA, announced that the U.S. Food and Drug Administration (FDA) has approved an update to the Neulasta® (pegfilgrastim) prescribing information. The update now allows for Neulasta to be used in patients with at least a 17% risk of febrile neutropenia as a side effect of chemotherapy. Previously, Neulasta was approved to treat patients with a risk of febrile neutropenia ranging from 30%–40%. The expanded label was based on studies that showed a significant risk of febrile neutropenia in patients receiving moderately myelosuppressive therapies as well as a reduction in incidence of hospitalization. Neulasta now can be used with the first cycle of moderately myelosuppressive therapy. For more information, visit www.neulasta.com/patient/index.jsp.

Therapeutic Regimen Is Simplified

Biogen Idec in Cambridge, MA, has implemented supplemental labeling changes to the Zevalin® (ibritumomab tiuxetan) therapeutic regimen. The update reduces the number of required gamma camera studies from two to one, making the Zevalin therapeutic regimen even more convenient. The studies are done to monitor the biodistribution of the therapy. The change will simplify care and give patients and doctors more flexibility. The drug is a treatment for patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin lymphoma (NHL) and also for patients with follicular B-cell NHL that is refractory to Rituxan® (rituximab, Genentech, Inc., South San Francisco, CA) therapy. Zevalin is a monoclonal antibody that is directed against the CD20 antigen found on the surface of malignant and normal B lymphocytes.

Biogen Idec also is updating the Zevalin product safety information to include a boxed warning with information stating that severe cutaneous and mucocutaneous reactions, some with fatal outcomes, are rare but have been reported. For more information, visit www.zevalin.com.

Drug Receives Full Approval for Adjuvant Breast Cancer Treatment

Arimidex® (anastrozole, AstraZeneca, Wilmington, DE) has received full FDA approval for the adjuvant treatment of early-stage hormone receptor-positive breast cancer following surgery in postmenopausal women. Anastrozole first was approved in 2002 as a supplemental new drug to treat early breast cancer in hormone receptor-positive postmenopausal women. After completion of further research, the drug now has been fully endorsed by the FDA as adjuvant treatment. Arimidex also is indicated for first-line treatment (first hormonal treatment in advanced breast cancer) for postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer, as well as for treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. To learn more about Arimidex, visit www.arimidex.com.

Priority Review Granted to Oral Aromatase Inhibitor Letrozole

Novartis Pharmaceuticals in East Hanover, NJ, recently announced that the FDA has granted priority review to Femara® (letrozole tablets) in the adjuvant (postsurgical) treatment of postmenopausal women with hormone receptor-positive early breast cancer.

The FDA grants priority review to products that potentially offer a significant improvement in the treatment, diagnosis, or prevention of a disease. Specifically, Femara showed significantly improved efficacy in women with node-positive disease and those who received chemotherapy treatment. Femara also demonstrated a significantly reduced risk of distant metastases compared with other drugs. Femara is most frequently used for extended treatment after tamoxifen but now is being considered for adjuvant treatment in early breast cancer. More information regarding the drug can be obtained by calling Novartis at 866-4FEMARA (toll free) or visiting www.us.FEMARA.com or www.us.novartisoncology.com.

U.S. Food and Drug Administration Approves Genetic Test for Colon Cancer Drug Response

The FDA recently approved a genetic test for detecting variations in the UGT1A1 gene that is responsible for metabolizing irinotecan. Irinotecan is a component of therapy indicated for treatment of colorectal cancer. Camptosar® (irinotecan, Pfizer Inc., New York, NY) previously changed its labeling to indicate that those with UGT1A1 polymorphism are at risk for greater side effects from the drug and need to be started at a lower dosage. Now the FDA has approved a test to determine who is at risk for greater side effects. The Invader® UGT1A1 Molecular Assay Test, manufactured by Third Wave Technologies in Madison, WI, can help physicians to determine how a patient may respond to irinotecan. With the new test available, patients can receive appropriate dosing for their specific genetic makeup and possibly decrease their risk for more severe side effects.

Manufacturer Changes Cetuximab Package Insert

Erbitux® (cetuximab, ImClone Systems Inc., New York, NY) is approved to be used in combination with irinotecan for the treatment of epidermal growth factor receptor-expressing, metastatic carcinoma in patients who are refractory to irinotecan-based therapy or as a single agent in patients who are intolerant to irinotecan therapy. New precautionary, adverse reaction, and additional warning statements have been added to the labeling.

ImClone has added the recommendation that patients be monitored for hypomagnesemia, hypocalcemia, and hypokalemia during and following treatment with Erbitux. In ongoing clinical trials, about half of all patients receiving Erbitux, either alone or in combination with other drugs, experienced

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some level of hypomagnesemia and accompanying hypocalcemia and hypokalemia. The half-life of the drug is approximately eight weeks; therefore, monitoring should continue for that duration. The second new recommendation is that patients experiencing an infusion reaction during Erbitux treatment should be observed longer than the currently advised one hour.

Manufacturer Changes Bevacizumab Packaging

Avastin® (bevacizumab, Genentech, Inc., South San Francisco, CA), a monoclonal antibody, is approved for use in combination with 5-fluorouracil–based chemotherapy for first-line treatment of patients with metastatic colorectal cancer. When chemotherapy fights the tumor, Avastin attacks the blood vessels that surround the tumor so that both drugs work in tandem to shrink tumors. The changes made to the labeling of bevacizumab include the addition of study findings indicating that patients who had disease progression following regimens containing both oxaliplatin and irinotecan showed an absence of activity in the third-line treatment. For refractory patients, the study indicates a 1% response rate with a regimen containing Avastin if they previously had progressive disease with the two other drugs.

U.S. Food and Drug Administration Approves Exemestane Tablets

The FDA recently approved Aromasin® (exemestane, Pfizer Inc., New York, NY) for the treatment of postmenopausal women with estrogen receptor-positive early breast cancer who have received two to three years of tamoxifen and are switched to exemestane for completion of a total of five consecutive years of adjuvant hormonal therapy. The study on which the approval for exemestane was based demonstrated that disease-free survival was significantly improved in the group that received exemestane compared to those who received tamoxifen. For complete prescribing information on exemestane, visit www.fda.gov/cder/foi/label/2005/020753s006lbl.pdf.

Manufacturer Issues Cardiotoxicity Warning for Breast Cancer Drug

Genentech, Inc., in South San Francisco, CA, released a letter to inform physicians about cardiotoxic events related to Herceptin® (trastuzumab) use. Genentech updated cardiotoxicity information related to the use of Herceptin, which was obtained from the National Surgical Adjuvant Breast and Bowel Project (NSABP) study (B-31), a randomized, phase III trial that was conducted in 2,043 women with operable, human epidermal growth factor receptor 2 overexpressing breast cancer (immunohistochemistry 3+ or fluorescence in situ hybridization positive). The study demonstrated a significant increase in cardiotoxicity in patients who were randomized to the Herceptin-containing arm as compared to patients who received chemotherapy alone. Final analysis of the cardiac safety data collected in the NSABP B-31 and North Central Cancer Treatment Group N9831 studies is ongoing. Herceptin as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease. Herceptin in combination with paclitaxel is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have not received chemotherapy for their metastatic disease.

NEW PRODUCTS

New Company Launches Vaginal Dilators

Soul Source Enterprises, LLC, in Portland, OR, is a new company with a product line of vaginal dilators. The dilators are made of silicone rubber, which makes them resilient, able to retain body heat, and easy to care for.

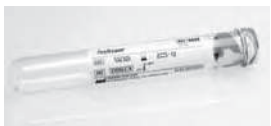
Soul Source dilators come in eight graduated sizes. They range in size from approximately 0.5 x 2.5 inches (smallest) to 1.625 x 6 inches (largest). Soul Source dilators are designed for use in progressive vaginal dilation therapy. Most frequently they are used to treat vaginismus, a painful condition of the vagina involving involuntary spasm of the muscles of the pelvic floor. Progressive vaginal dilation therapy also is used effectively for treating genital pain conditions. Soul Source dilators are stable from –50° to 340°F. They may be chilled, used at room temperature, or warmed. The dilators have been used successfully in addressing postsurgical vaginal swelling and for the effects of radiation therapy. To read more about Soul Source vaginal dilators or for ordering information, visit www.soulsourceenterprises.com.

Prostate Cancer Screening Test Being Developed

An experimental prostate cancer screening method that measures specific antibodies in the blood appears to be more sensitive and more specific than prostate specific antigen (PSA) testing. In a study evaluating the accuracy of the test in serum samples from patients with prostate cancer and controls, the test had 88.2% specificity and 81.6% sensitivity for prostate cancer. It also was significantly better than PSA at detecting cancer. Unlike PSA tests, which look for levels of an antigen against the background of other proteins, the 22-phage-peptide detector uses the immune system to detect small quantities of a protein and amplify a response to that protein.

The next step for the investigators is to validate the test against a larger group of samples from other institutions. If the test holds up in further studies, commercialization would be relatively simple because it requires only a routine blood draw.

Collection Tube Available for Preservation of Tumor Cells



Veridex, LLC, a Johnson and Johnson company in Warren, NJ, has developed a collection system for tumor cell analysis. The new collection tube stabilizes circulating tumor cells (CTCs) for as many as 72 hours at room temperature. CTCs are fragile and tend to disintegrate in just a few hours when collected in standard blood collection tubes. The CellSave® preservative tube gives cells improved assay reproducibility and allows shipment of samples from remote sites for testing.

The CellSave preservative tube represents a breakthrough in CTC analysis. Containing an optimized cell preservative, the CellSave preservative tube provides stability for blood samples.

CD Provides Medical Information in Case of Emergency

My Medical CD® (Winnipeg, Canada) is a unique product that enables a person to carry his or her essential medical information on a mini CD that fits in a wallet, pocket, or purse. When an accident or other medical emergency has occurred, medical attending personnel can place the CD into a personal computer; the CD self-loads, and the patient's emergency medical information appears on the monitor. The emergency information section is not password protected so that the patient can receive aid without being conscious or able to communicate.

If the patient can supply his or identification tag and password, access to the medical history section is achieved. The medical history section contains detailed information about the patient. Information recorded could include a doctor's name and telephone number, the patient's address, and prior medical conditions.

To obtain My Medical CD, an application, available on the My Medical CD Web site (www.MyMedicalCD.com) or from a company representative, must be completed.

My Medical CD also can be used to track travel information such as passport numbers and other travel documents, making it

useful for more than just medical history. My Medical CD is available for an initial purchase price and an additional yearly maintenance fee.

Sleepwear Helps Women Recovering From Cancer Treatment

Wildbleu™ sleepwear (Seattle, WA) is being marketed for women who experience side effects of chemotherapy or medication such as tamoxifen, which may precipitate hot flashes or night sweats. Wildbleu performance sleepwear is a cooling fabric made of 100% Dri Release®, a blend of polyester and cotton that wicks away moisture from the skin. The fabric pushes the moisture to the surface of the garment, where it dries quickly. An odor eliminator also is embedded in the garment. The fabric is soft and comes in a variety of styles and colors. To view the Wildbleu catalog, visit www.wildbleu.com.

Brochure Assists Patients After Diagnosis

The Agency for Healthcare Research and Quality (AHRQ) recently published a brochure to aid patients in seeking information they need after a diagnosis of a medical condition. The main focus of diagnosis in the brochure is to help patients with cancer, but it also can be used for patients with other medical diagnoses. The main purpose of this educational tool is to assist patients in making informed choices regarding their health care. The information is presented simply and organized efficiently so patients can scan it and read only the information they need. A free brochure is available as a PDF download or can be ordered electronically from the AHRQ Web site at www.ahrq.gov/consumer/diaginfo.htm.

RECALL ALERTS

Fluorouracil Lots Are Recalled

American Pharmaceutical Partners, Inc., in Schaumberg, IL, has voluntarily recalled various lots of fluorouracil injection 50 mg/ml. The company decided to take the action as a result of an investigation indicating the vials may contain glass particles. The product code number is 101710, lot numbers range from 140493–200500, and they were distributed from July 27, 2004, to August 19, 2005. For the complete recall information, visit the FDA Web site at www.fda.gov/medwatch/safety/2005/Fluorouracil_productrecall.pdf.

NOTEWORTHY

New Guidelines for Breast Cancer Testing Have Been Released

The U.S. Preventive Services Task Force recently issued guidelines concerning genetic counseling and routine testing for people with breast and ovarian cancer predisposition. With improving technology, consumers are demanding the most recently available tests that may not always be appropriate. The guidelines take into consideration ethnic background and outline high-risk familial patterns that may indicate a more significant need for testing. Family history is the strongest indicator of high risk that can be discovered through genetic testing. When identified, it is important that woman are referred to trained healthcare professionals and genetic counselors who can assist them with informed decision making about genetic testing and available treatment options. The guidelines were published in the September 6, 2005, issue of *Annals of Internal Medicine.* The full recommendations with background can be viewed on the Agency for Healthcare Research and Quality Web site at www.ahrq.gov/clinic/uspstf05/brcagen/brcagenrs.htm.