PRODUCT UPDATE

Valerie Burger, RN, MA, MS, OCN®
Associate Editor

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

Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.*

Digital Object Identifier: 10.1188/06.ONF.153-155