

PHARMACY CORNER

Panel Recommends Anastrozole for Adjuvant Breast Cancer Therapy

The American Society of Clinical Oncology (ASCO) has issued guidelines on the use of aromatase inhibitors as adjuvant therapy for women with hormone receptor-positive breast cancer. Overall, the panel considered the results of the Arimidex® (anastrozole, AstraZeneca Pharmaceuticals, Wilmington, DE), tamoxifen, alone or in combination (ATAC) trial and its extensive supporting data to be very promising and encouraged healthcare providers to discuss the results with their patients. Although the panel stated that recommending a wholesale switch from the standard use of tamoxifen in the adjuvant setting would be premature, it encouraged healthcare providers and patients to come to their own conclusions after considering all available data.

The ASCO panel also stated that Arimidex is the only aromatase inhibitor with clinical trial data in the adjuvant setting and should be considered the preferred agent if an aromatase inhibitor is to be used. The National Comprehensive Cancer Network, an alliance of the world's leading cancer centers, updated its breast cancer guidelines in February 2002 to include information on the ATAC trial and recommended that these results be discussed with patients.

The U.S. Food and Drug Administration currently approves Arimidex for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer and treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy.

Because Arimidex can cause fetal harm, pregnancy must be excluded before starting treatment. Common side effects observed in clinical trials included hot flashes, nausea, asthenia, pain, back and bone pain, and increased cough. Joint pain and stiffness also have been reported.

For more information and full prescribing information on Arimidex, please visit the AstraZeneca Web site at www.astrazeneca-us.com.

Panel Evaluates Use of Aromatase Inhibitors for Breast Cancer Treatment

The American Society of Clinical Oncology (ASCO) convened a blue ribbon panel to review the use of aromatase inhibitors in the adjuvant and first-line treatment settings for advanced breast cancers.

Specific to the adjuvant breast cancer treatment setting, the panel reviewed the Arimidex® (anastrozole, AstraZeneca Pharmaceuticals, Wilmington, DE), tamoxifen, alone or in combination (ATAC) trial data and did not recommend the use of aromatase inhibitors at that time because of a lack of compelling and mature data. However, Novartis Pharmaceuticals (East Hanover, NJ) was encouraged that the panel recognized the importance of this category. Novartis is looking forward to the results of its ongoing letrozole (Femara®) adjuvant studies, which should provide data that will enable the panel to move forward with its recommendations. Results are expected in 2004.

Data comparing Femara and Arimidex were presented at this year's ASCO meeting and at the San Antonio Breast Cancer Symposium (SABCS) in December 2001. Fifty percent more women responded to Femara than Arimidex in the second-line treatment setting. No statistically significant differences in time to disease progression (primary endpoint) or other endpoints were observed. Data presented at the SABCS showed that in the first-line advanced breast cancer treatment setting, Femara offered a statistically greater early survival advantage throughout the first two years of therapy compared to tamoxifen. In addition, approximately five years after initiation of the study, more women who had begun therapy with Femara were still alive and free of tumor progression compared to those who had started on tamoxifen. No differences were observed in duration of tumor response or overall survival.

Additional data from another study presented at the SABCS demonstrated that Femara might be more effective than tamoxifen in treating postmenopausal women with estrogen receptor- and HER2-positive breast cancers. The results are important because HER2-positive breast cancers in postmenopausal women are especially difficult to treat.

Furthermore, results of the largest neoadjuvant (preoperative) trial evaluating endocrine agents demonstrated that Femara is a

more effective therapy for postmenopausal women with hormone-receptor positive tumors than tamoxifen. In 324 postmenopausal women with hormone-sensitive breast cancer, the number of clinical responses was significantly higher for Femara than for tamoxifen and significantly more women on Femara underwent breast-conserving surgery compared to those receiving tamoxifen.

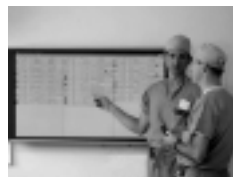
Femara, an aromatase inhibitor, is an oral, once-a-day, first-line treatment for postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer. Femara also is approved for the treatment of advanced breast cancer in women with disease progression after prior antiestrogen therapy. Femara generally is well tolerated, and adverse reactions rates in the first-line study that compared Femara to tamoxifen were similar to those seen in second-line studies. The most commonly reported adverse events for Femara were bone pain, hot flushes, back pain, nausea, dyspnea or labored breathing, arthralgia, fatigue, coughing, constipation, chest pain, and headache. The incidence of peripheral thromboembolic events, cardiovascular events, and cerebrovascular events was 2%.

For more information on Femara, visit the Novartis Web site at www.novartis.com.

NEW PRODUCTS

New System Displays Critical-Path Information on a Real-Time Basis

The Health Enterprise Navigator® (NaviCare Systems Inc., St. Paul, MN) system is a suite



of Windows®-based applications designed to collect and display critical-path information on a real-time basis within departments and enterprise-wide. Health Enterprise Navigator interfaces with existing departmental

Description of products does not indicate or imply endorsement by the Oncology Nursing Forum or the Oncology Nursing Society.

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