New Clinical Trial to Investigate Treatment Options After Tamoxifen

Researchers to Evaluate Exemestane (Aromasin®) in a Phase III Trial
for the Treatment of Breast Cancer

Pittsburgh, PA – (May XX, 2001) The National Surgical Adjuvant Breast and Bowel Project (NSABP) has launched a new Phase III clinical trial that will evaluate exemestane (AROMASIN®), in 3,000 postmenopausal women diagnosed with estrogen-receptor-positive breast cancer who have completed five years of tamoxifen (Nolvadex®) therapy. Known as Protocol B-33, the trial will determine whether exemestane will prolong disease-free survival and overall survival in women already treated for breast cancer. Over 100 sites in the United States, Canada, and Puerto Rico are expected to take part in the trial.

Exemestane (AROMASIN), developed and marketed by Pharmacia Corporation, is currently approved for the treatment of advanced breast cancer in postmenopausal women whose tumors have stopped responding to tamoxifen. It is the first and only oral drug in a class of therapies called aromatase inactivators that selectively target and irreversibly inactivate the aromatase enzyme, which is required to produce estrogen. This unique mechanism of action reduces the supply of estrogen to cancerous cells and prevents the cells from continuing to grow. This contrasts with aromatase inhibitors that only temporarily inhibit the aromatase enzyme.

- more -
“This study could potentially ease women’s concerns regarding breast cancer recurrence and what treatment options are available after tamoxifen therapy is complete,” said Dr. Roy Smith, NSABP director of medical affairs and oversight, and protocol officer for B-33.

A majority of patients treated with tamoxifen are disease-free after five years of therapy. However, some of these patients harbor small tumor cells even after several years of tamoxifen therapy, which could spread to another part of the body and cause a recurrence of cancer after therapy is completed.

“This trial is unique in that it offers a therapy for women who have not had a recurrence of cancer and who have completed standard anti-estrogen therapy with tamoxifen,” said Dr. Terry Mamounas, B-33 protocol chair. “Sequential treatment with exemestane immediately following tamoxifen therapy may continue to treat hormone sensitive tumors. Tamoxifen is the standard adjuvant hormonal therapy for women with breast cancer. However, studies have shown that tamoxifen offers the greatest benefit when taken for only five years.”

In the trial, women who have completed five years of tamoxifen therapy will be randomly assigned to take 25 mg of exemestane daily for two years or placebo. The most commonly reported side effects associated with exemestane include mild to moderate hot flashes, nausea, and fatigue.

For more information on B-33 or to locate a participating institution, call the National Cancer Institute’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or visit the NSABP Web site at http:\www.nsabp.pitt.edu.

The NSABP is a nonprofit, clinical trial cooperative group, which includes a network of over 3000 professionals located in the U.S., Canada and Puerto Rico. Research conducted by the NSABP is supported primarily by grants from the NCI. For more than 40 years, the NSABP has successfully conducted large-scale, randomized clinical trials in breast and colorectal cancer that have altered and improved the standard of care for women and men with these diseases.

###