



*National Surgical Adjuvant  
Breast and Bowel Project*

Norman Wolmark, MD  
*Chairman*

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FOR IMMEDIATE RELEASE

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## **WOMEN WITH NON-INVASIVE BREAST CANCER SOUGHT FOR NEW CLINICAL TRIAL**

*Researchers to Compare the Effectiveness of Anastrozole (ARIMIDEX®) to Tamoxifen (NOLVADEX®) to Reduce Recurrence in Patients with Very Early Stage Breast Cancer*

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**Pittsburgh, Pa. – May 15, 2003** – The National Surgical Adjuvant Breast and Bowel Project (NSABP) has launched a new Phase III clinical trial to evaluate the effectiveness of anastrozole (ARIMIDEX®) compared to tamoxifen (NOLVADEX®) with radiation therapy in preventing recurrence of breast cancer in women with primary ductal carcinoma in situ (DCIS). The study, known as B-35, will also compare the impact of each drug on a patient's symptoms and quality of life. The trial will enroll 3,000 postmenopausal women with DCIS who have undergone lumpectomy at more than 150 centers across the United States and Canada. The DCIS must be estrogen-receptor-positive or progesterone-receptor-positive.

Ductal carcinoma in situ is breast cancer in its earliest stage. In situ refers to the fact that the cancer involves only the cells lining breast ducts and does not involve nearby breast tissue or lymph nodes. If untreated, invasive breast cancer may develop. According to the American Cancer Society, 45,000 women will be diagnosed with DCIS in 2003. In recent years, DCIS has been diagnosed more frequently due to the increased use of screening mammography.

This trial represents the first time that a new drug other than tamoxifen is being studied for DCIS. "Studies have proven the effectiveness of anastrozole in the treatment of early breast cancer," said Thomas Julian, M.D., protocol officer for B-35. "It is our hope that this study will prove that the drug can also reduce the recurrence of DCIS or the development of invasive breast cancer, with minimal impact on a patient's quality of life."

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Anastrozole is a drug that works by preventing an enzyme, aromatase, from producing estrogen. Currently, anastrozole is the only hormonal drug other than tamoxifen to be approved by the U.S. Food and Drug Administration (FDA) for early breast cancer. The ATAC trial (Arimidex, Tamoxifen Alone or in Combination trial)—the world’s largest early breast cancer treatment study involving more than 9,300 postmenopausal women in 21 countries—showed a statistically significant improvement in recurrence free survival in the anastrozole arm as compared to tamoxifen.

“Anastrozole has shown significant improvements over tamoxifen, especially in terms of safety and efficacy,” said Richard Margolese, MD, protocol chair for B-35. “We believe it has the potential to be an important treatment option for women with DCIS.”

Participants in the B-35 trial will be randomly assigned to receive either 1 mg of anastrozole plus placebo, or 20 mg of tamoxifen plus placebo daily for five years. They also will begin radiation therapy after being assigned to one of the treatment groups. Participants will obtain regular follow-up examinations including a mammogram and gynecologic exam. Further, women will complete questionnaires in order to determine how the drugs affect a woman’s quality of life.

Anastrozole and tamoxifen, manufactured by AstraZeneca Pharmaceuticals, Wilmington, Del., will be provided to study participants at no cost.

For more information about NSABP Protocol B-35, or to locate a participating institution, call the National Cancer Institute’s (NCI) Cancer Information Service at 1-800-4-CANCER (1-800-422-6237); for individuals with TTY equipment the number is 1-800-332-8615. Information also is available on the NSABP Web site at [www.nsabp.pitt.edu](http://www.nsabp.pitt.edu) or the NCI’s Web site at <http://cancertrials.nci.nih.gov>.

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The NSABP is a not-for-profit, clinical trials cooperative group, which includes a network of over 300 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 colorectal and breast cancer that have altered and improved the standard of care for men and women with these diseases.

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