



Coast to Coast

Published by the National Surgical Adjuvant Breast and Bowel Project (NSABP) for BCPT participants

No Cost Tamoxifen Program Announced for BCPT Women on Placebo

Participants who were assigned to the placebo arm of the *Breast Cancer Prevention Trial* (BCPT) in the United States now have the opportunity to receive Nolvadex (tamoxifen citrate) at no cost through a new program. This program has been developed through the collaborative efforts of AstraZeneca (formerly Zeneca Pharmaceuticals), the manufacturer of Nolvadex, and the National Surgical Adjuvant Breast and Bowel Project (NSABP). It was formed to handle drug distribution for those participants assigned to receive placebo in the BCPT who are interested in receiving Nolvadex to reduce their incidence of breast cancer. AstraZeneca has contracted with Express Scripts, Inc. (ESI), a mail-order pharmacy, to distribute Nolvadex to those BCPT participants assigned to receive placebo who are interested in this program and are prescribed the drug by a physician.

For participants who so wish, but who have not started taking Nolvadex or tamoxifen citrate for the purpose of reducing their incidence of breast cancer, AstraZeneca will provide Nolvadex through this program for 5 years in increments of 6-month supplies. Some participants, however, may already have started on Nolvadex or tamoxifen citrate for the purpose of reducing their incidence of breast

cancer. For these women, AstraZeneca will provide Nolvadex at 6-month intervals for the remainder of the 5-year treatment. (For example, if, with your doctor's permission, you have taken Nolvadex or tamoxifen citrate for one year, AstraZeneca will provide you with Nolvadex for up to 4 years under this program.) If you were a BCPT participant assigned to the placebo arm and developed breast cancer while on the trial, AstraZeneca will also provide you with Nolvadex for up to 5 years if your physician writes a prescription.

The program will not reimburse BCPT participants assigned to receive placebo for any out-of-pocket expenses incurred while taking Nolvadex or tamoxifen citrate prior to entering this program. In addition, participants who enter this program must agree in writing that they will not seek reimbursement for any Nolvadex received through ESI from any federal or state programs, including Medicare, Medicaid or any state pharmaceutical assistance programs; or any private third-party payer, such as an HMO or insurance company.

Regretfully, at this time BCPT participants assigned to receive placebo who live in Canada will not be able to receive tamoxifen through this program. In Canada, tamoxifen has not been approved for the reduction of breast

Inside this issue

NSABP Launches Its Second Breast Cancer Prevention Trial, STAR.....Pg. 2

Capital Area SERM Study seeks participants.....Pg. 2

NSABP Publications.....Pg. 3

6 Important Steps for Participants on Placebo to Recieve No Cost Tamoxifen.....Pg. 4

The National Surgical Adjuvant Breast & Bowel Project (NSABP) headquarters is located in Pittsburgh, PA.

**Contact us by mail at:
NSABP Operations Center
Dept. of Public Relations
& Communications
East Commons
Professional Building
5th Floor
Pittsburgh, PA 15212**

**Or visit our Web Site at
www.nsabp.pitt.edu**

Continued on Pg. 4...

NSABP Launches Its Second Breast Cancer Prevention Trial, STAR

On May 25, 1999 at a national press conference in Washington, DC, researchers announced that they would begin to recruit volunteers at more than 500 centers across the United States, Puerto Rico, and Canada for the *Study of Tamoxifen And Raloxifene* (STAR). Many women who were assigned to placebo in the *Breast Cancer Prevention Trial* (BCPT) are eligible for STAR, and as of October 31, 1999, 508 of these women have enrolled. If you are postmenopausal and were on placebo, contact your BCPT coordinator for details.

What is STAR?

STAR is the NSABP's second breast cancer prevention trial and will include 22,000 postmenopausal women age 35 or older who are at increased risk for developing breast cancer. The study will compare the proven benefits of tamoxifen against the promising results of raloxifene to determine whether raloxifene can also reduce the incidence of breast cancer, but with fewer side effects. Based on the findings of the BCPT, tamoxifen (Nolvadex®) received approval from the US Food and Drug Administration (FDA) to reduce the incidence of breast cancer; raloxifene (Evista®) has FDA approval for the treatment and prevention of osteoporosis (brittle bones). In STAR, increased risk of breast cancer will be determined by a computerized calculation based on a woman's current age, her age at first menstrual period, her age at first live birth, her family history of breast cancer, and her personal medical history of breast disease. Women who have been diagnosed with lobular carcinoma in

situ (LCIS) are eligible for STAR based on this factor alone.

STAR is limited to postmenopausal women because the drug raloxifene has yet to be adequately tested for long-term safety in premenopausal women. However, the National Cancer Institute (NCI) is currently seeking 62 participants residing in the Mid-Atlantic states for a new Phase II study that will evaluate raloxifene's safety in

Light Reading

The following is a list of NSABP publications related to tamoxifen and/or the BCPT that may be of interest to you. For a brief overview of each article please visit the *Bibliography* on our Web Site at www.nsabp.pitt.edu.

NCI Sponsored SERM Study for Premenopausal Women

The *Capital Area SERM Study* seeks 62 premenopausal women ages 23 to 47 at increased risk for developing invasive breast cancer. Conducted by the National Cancer Institute (NCI) and the National Naval Medical Center, this three-year Phase II trial will evaluate the safety of raloxifene, a selective estrogen receptor modulator (SERM).

SERMs have estrogen-like effects in some tissues such as bone and blood fats, and anti-estrogen effects in other tissues such as the uterus and breasts. SERMs may be helpful in reducing the risk of breast cancer by blocking estrogen's effect in breast tissue.

The primary goal of this new study is to evaluate raloxifene's effect on bone mineral density in premenopausal women. It will also study raloxifene's effect on participant hormone and lipid levels, menstrual cycle, uterus and ovaries, breast density, and health-related quality of life.

To be eligible for this study, one of the following criteria must also apply: a Gail model risk of at least 1.7% over 5 years; lobular carcinoma in situ (LCIS); atypical ductal hyperplasia plus a family history of breast cancer; ductal carcinoma in situ (DCIS) that has been treated with mastectomy, or lumpectomy and radiation; BRCA 1 or 2 gene mutation; or a strong family history of breast cancer. Additionally, participants must use nonhormonal methods of contraception; have regular menstrual cycles; not have a known allergy to raloxifene; and not have a history of infertility, cirrhosis of the liver, bleeding disorders or blood clots.

Participants will be enrolled to one of two sequential groups; the standard, 60 mg dose or a 300 mg dose of raloxifene that will be taken by mouth daily for two years. After enrollment, participants will be asked to travel approximately four times within the first year to the National Institutes of Health Clinical Center or the National Naval Medical Center, both located in Bethesda, Maryland, to receive regularly scheduled checkups and tests. Additional follow-up exams will be scheduled annually for the remainder of this three-year trial.

Women interested in participating in the study should call the NCI's **Clinical Studies Support Center toll free at 1-888-624-1937**, Monday through Friday, 9:00 a.m. to 5:00 p.m., Eastern time.

Weighing the Risks and Benefits of Tamoxifen Treatment for Preventing Breast Cancer

By.....Mitchel H. Gail, MD, PhD, *et al*
Published in.....Journal of the
National Cancer Institute
91:21:1829-1846, Nov. 1999

Validation Studies for Models Projecting the Risk of Invasive and Total Breast Cancer Incidence

By...Joseph P. Constantino, DrPH,*et al*
Published in.....Journal of the
National Cancer Institute
91:18:1541-1548, Sept. 1999

Health-Related Quality of Life and Tamoxifen in Breast Cancer Prevention: A Report From the National Surgical Adjuvant Breast and Bowel Project P-1 Study

By.....Richard Day, PhD, *et al*
Published in.....Journal of
Clinical Oncology
17:9:2659-2669, Sept. 1999

Tamoxifen for Prevention of Breast Cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study

By.....Bernard Fisher, MD, *et al*
Published in.....Journal of the
National Cancer Institute
90:18:1371-1388, Sept. 1998

Long-term Tamoxifen Citrate Use and Potential Ocular Toxicity

By...Michael B. Gorin, MD, PhD, *et al*
Published in.....American Journal
of Ophthalmology
125:4:493-501, April 1998

Participants Strengthen Clinical Trial Research: The Vital Role of Participant Advisors in the Breast Cancer Prevention Trial

By...Lori Psillidis (Garvey), M.Ed., *et al*
Published in.....Journal of
Women's Health
2:2:227-232, April 1997

the premenopausal population. Please see the related article on page two for more information.

Once enrolled in STAR, a woman will be randomly assigned to receive either tamoxifen or raloxifene daily for five years; neither she nor her doctor will know what drug she is taking. All women will take two pills a day: half will take 20 mg of tamoxifen and a raloxifene placebo (an inactive pill that looks like raloxifene); the other half will take 60 mg of raloxifene and a tamoxifen placebo (an inactive pill that looks like tamoxifen). All women in STAR will receive an active drug, either tamoxifen or raloxifene. As in the BCPT, all participants' health will be closely monitored through regular follow-up examinations that include a mammogram and a gynecologic exam, for at least seven years.

What will researchers learn from STAR?

The main goal of STAR is to determine how raloxifene compares to tamoxifen in reducing invasive breast cancer in high risk women. However researchers will also look at the effect of both drugs on the incidence of noninvasive breast cancer, endometrial cancer, heart disease, and bone fractures. The effect they have on quality of life and their side effects will also be documented.

“Each One Reach One”

Researchers estimate that it will take at least 5 years to enroll the 22,000 women required to complete this study. At this time (December 20, 1999), 2,511 women have enrolled in STAR. This represents slightly over 11% of the total number of women needed. Of the women who have had their breast cancer risk evaluated, almost 10% are from a racial or ethnic minority group. The NSABP remains determined to educate more women from racial and ethnic minority populations about the

early detection of breast cancer and prevention, and efforts are underway to meet this challenge. So many P-1 participants were helpful in the recruitment

“You still remain our best spokespeople and can continue to help by telling your friends, co-workers, and family, about STAR.”

process for the BCPT and referred friends and family members to that trial. You still remain our best spokespeople and can continue to help by telling your friends, co-workers, and family, about STAR. For additional details, we invite you to visit the NSABP's Web Site at <http://www.nsabp.pitt.edu> or the National Cancer Institute's clinical trials Web Site at <http://cancertrials.nci.nih.gov>. To locate a STAR center in the United States and Puerto Rico, please call the National Cancer Institute's (NCI's) Cancer Information Service at 1-800-4 CANCEER (1-800-422-6237). In Canada, call the Canadian Cancer Society's (CCS's) Cancer Information Service at 1-888-939-3333. ●

No Cost Tamoxifen Program Announced... (cont.)

cancer incidence in women at high risk for developing the disease.

AstraZeneca, the NSABP and Canadian authorities are working to overcome this barrier. Canadian participants will be notified of any updates regarding this process in the upcoming months.

The NSABP and AstraZeneca are proud to introduce this program and thank you for your patience as we developed the process. Please follow the instructions in the highlighted portion below to become a part of this program. Any questions regarding this process should be directed to ESI at 1-800-830-2538. ●

Follow these 6 steps to receive Nolvadex through this new program:

- 1- To begin receiving Nolvadex, please contact ESI by calling 1-800-830-2538.
- 2- ESI will obtain your name, address, and social security number. ESI will contact the NSABP to verify the names of the BCPT participants assigned to receive placebo who are interested in taking part in the program.
- 3- Once the participant's status has been confirmed, ESI will forward a mailer and detailed instructions to the woman that she should take to her doctor. The doctor will need to write a prescription for a 6-month supply of Nolvadex 20 mg tablets (one tablet to be taken each day). The prescription and the completed mailer should be sent to ESI for drug distribution. You will have to obtain a new prescription for this same dosage from your doctor every 6 months in order to receive your next shipment of drug.
- 4- In order to receive Nolvadex through this special program, you must enroll in the program by Friday, April 28, 2000.
- 5- If you have not been taking Nolvadex or tamoxifen citrate already, the program will last 5 years beginning from the date of your first prescription. If you have already been taking Nolvadex or tamoxifen citrate for the purpose of reducing the incidence of breast cancer or for the treatment of breast cancer, you will be eligible to receive the drug for the remainder of the 5-year treatment, as long as your doctor continues to prescribe the drug for you.
- 6- Once enrolled, you must inform ESI of any changes in your name, address, or phone number, in order to continue receiving the drug shipments.

Coast to Coast

The NSABP, with a membership of more than 6,000 medical professionals, has successfully conducted large-scale, randomized clinical research trials for more than 40 years. Results from NSABP studies have changed the way breast cancer is treated and potentially prevented.