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**STAR Enrolls 6,139 Women in First Year;
16,000 More Women at Increased Risk of Breast Cancer Sought**

Six thousand in, sixteen thousand to go.

The first year of the Study of Tamoxifen and Raloxifene (STAR) saw 6,139 postmenopausal women at increased risk of breast cancer enroll in this landmark prevention study – and more than 47,000 women went through an individualized, no-obligation risk assessment to determine their risk of breast cancer and weigh the pros and cons of joining the trial. Enrollment began July 1, 1999.

Many of these 47,114 women did not have an increased risk of breast cancer that would have made them eligible for the trial; 29,303 women were eligible for the trial based on breast cancer risk alone, but had to make the choice to participate based on their overall health and personal reasons.

STAR is designed to determine whether the osteoporosis prevention and treatment drug raloxifene (Evista®) is as effective as tamoxifen (Nolvadex®) in reducing breast cancer risk. In 1998, tamoxifen was shown to reduce the chance of developing breast cancer by about half in the Breast Cancer Prevention Trial (BCPT), a study of over 13,000 premenopausal and postmenopausal women at increased risk of breast cancer. The U.S. Food and Drug Administration (FDA) approved the use of tamoxifen to reduce the incidence of breast cancer in women

A Study of
the National
Surgical
Adjuvant
Breast and
Bowel Project
(NSABP)
supported by
the National
Cancer
Institute

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at increased risk of the disease in October 1998. Raloxifene was shown to reduce the incidence of breast cancer in a large osteoporosis trial, the MORE study.

More than 500 centers across the United States, Puerto Rico, and Canada are enrolling participants in STAR. STAR is a study of the National Surgical Adjuvant Breast and Bowel Project (NSABP) and is supported by the U.S. National Cancer Institute (NCI).

NSABP Chairman Norman Wolmark, M.D., said, “We are pleased that so many women have joined this trial to help us answer this important medical question. We encourage women to go through the risk assessment process to learn more about their breast cancer risk and about STAR. In the end, each woman who joins does so for her own reasons, but every single woman plays a vital role.”

Lonnie Williams, co-chair of the Participant Advisory Board of STAR, lost her 42-year-old daughter to breast cancer and was a part of the BCPT – the first woman in Oklahoma City to join that study. When the trial was finished in April 1998, she found out she had been on a placebo. This made her eligible to either participate in STAR or to receive free tamoxifen from AstraZeneca Pharmaceuticals, the company that makes the drug and which had promised to provide tamoxifen without charge to all the BCPT participants on placebo treatment. She chose STAR.

“I believe in clinical trials,” said Williams. “And the trials being conducted by NSABP to prevent breast cancer are very important to all women. Having lost a daughter to breast cancer, which left a little boy to grow up without his mother, I feel that it is necessary that I do anything I can to help prevent this from happening to other women.”

As in the BCPT, women can join STAR if they have an increased risk of developing breast cancer equivalent to the risk of an average 60-year-old woman. These women have a 1.7 percent risk of breast cancer in five years, meaning that about 17 of them in 1,000 would be expected to develop breast cancer within five years. The women who are actually choosing to join the trial, as a group, exceed that minimum requirement.

Postmenopausal women of all ethnicities and races are encouraged to participate in STAR, and about 5 percent of the first 6,000 women in STAR are minorities. In this first year of STAR, a total of 6,636 minority women went through the risk assessment process, 1,812 had an

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increased risk of breast cancer that would qualify them for the study, and 281 have already decided to join.

In contrast, in the entire five years of enrollment for the BCPT, a total of 8,525 minority women went through the risk assessment process, 2,979 were risk-eligible, and 486 joined the trial.

The NSABP has undertaken several novel strategies to encourage minority women to participate in STAR, which include the STAR Community Outreach Program for Education (SCOPE) under way in ten cities in the United States. The goal of SCOPE is to educate minority women about breast cancer, which may ultimately lead to their more widespread participation in clinical trials.

Moreover, STAR is supported by the National Medical Association (NMA), a network of more than 20,000 African-American physicians. As a first effort, the NSABP is working closely with Region II of the NMA, which includes members in Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and the District of Columbia, to pilot a unique outreach project. The initial participation is in Philadelphia with plans to extend outreach into the rest of Region II and eventually throughout the NMA organization.

Recent analyses of the use of tamoxifen in women with breast cancer show that tamoxifen works equally well in white and African-American women. Wortia McCaskill-Stevens, M.D., of the NCI's Division of Cancer Prevention, who presented this research at the May 2000 meeting of the American Society of Clinical Oncology, notes that "The benefits and risks of tamoxifen are the same in African-American and white women. Women of all races can feel comfortable about considering STAR if they are at increased risk of breast cancer."

NCI is also working with the U.S. Indian Health Service and local Native American tribes to increase awareness and improve understanding about clinical research, including specific clinical trials such as STAR

Women who participate in STAR must be postmenopausal, at least age 35, and have an increased risk of breast cancer as determined by their age, family history of breast cancer, personal medical history, age at first menstrual period, and age at first live birth. They will also go through a process known as informed consent, during which they will learn about the potential benefits and risks of tamoxifen and raloxifene before deciding whether to participate in STAR.

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Tamoxifen and raloxifene may also increase a woman's chances of developing several rare, but potentially life-threatening health problems: deep vein thrombosis (blood clot in a large vein) and pulmonary embolism (blood clot in the lung). Tamoxifen use may also increase a woman's risk of stroke and endometrial cancer (cancer of the lining of the uterus) at a rate similar to estrogen replacement therapy. In ongoing studies, raloxifene has not been associated with an increased risk of endometrial cancer. STAR will help further define the risks and benefits of tamoxifen and raloxifene therapy.

Once a woman decides to participate, she is randomly assigned to receive either 20 mg tamoxifen or 60 mg raloxifene daily for five years and has regular follow-up examinations, including mammograms and gynecologic exams.

The maker of tamoxifen, AstraZeneca Pharmaceuticals, Wilmington, Del., and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Ind., are providing their drugs for the trial without charge. Eli Lilly and Company has also given NSABP a \$36 million five-year grant to defray recruitment costs at the participating centers.

First Year Recruitment Data

- During the first year of the trial, which started enrolling women on July 1, 1999, 47,114 women went through the risk assessment process. Of these women, 29,303 were eligible for the trial based on breast cancer risk alone. Of those risk-eligible women, 6,139 chose to participate.
- In the first year, 3,786 African-American women went through the risk assessment process, 739 were risk-eligible, and 103 joined STAR. About 1.7 percent of the women on STAR are African-American.
- In the first year, 1,688 Hispanic/Latina women went through the risk assessment process, 464 were risk-eligible, and 81 joined STAR. About 1.3 percent of the women on STAR are Hispanic/Latina.
- In the first year, 1,162 women who defined themselves as representing another minority population, such as Native American or Asian American, went through the risk assessment process, 609 were risk-eligible, and 97 joined STAR. About 1.6 percent of the women on STAR are ethnic minorities other than African-American or Hispanic/Latina.
- Of the 6,139 women joining STAR, 1,126 were from the placebo group of the Breast Cancer Prevention Trial.

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- More than half of the women joining STAR had had a hysterectomy prior to enrolling (52.3 percent). Women who have had a hysterectomy are not at risk for endometrial cancer.
- The breast cancer risk of women joining STAR in the first year has been above the minimum 1.7 percent risk of developing the disease within the next five years.

<u>Five-Year Breast Cancer Risk</u>	<u>Percent of women in STAR</u>
1.7- 2.0 percent	10.3 percent
2.0-2.9 percent	30.3 percent
3.0-4.9 percent	32.2 percent
Greater than 5.0 percent	27.2 percent

- Women joining STAR must be postmenopausal and at least 35 years of age. The ages of women joining STAR in the first year:

<u>Age</u>	<u>Percent of women in STAR</u>
35-49	9.4 percent
50-59	50.2 percent
60+	40.4 percent

- In the first year, 7.9 percent of the women joining STAR had had a diagnosis of lobular carcinoma in situ (LCIS), a condition that is not cancer, but which indicates an increased chance of developing invasive breast cancer.
- Number of women who joined STAR by U.S. state and Canadian province:

U.S. States (and Puerto Rico)

Alabama	20	Illinois	333
Arizona	77	Indiana	119
Arkansas	8	Iowa	136
California	359	Kansas	132
Colorado	110	Kentucky	83
Connecticut	96	Louisiana	76
Delaware	31	Maine	27
District of Columbia	23	Maryland	72
Florida	159	Massachusetts	155
Georgia	55	Michigan	259
Hawaii	41	Minnesota	151
Idaho	26	Mississippi	27

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Missouri	255	Rhode Island	10
Montana	41	South Carolina	131
Nebraska	63	South Dakota	47
Nevada	38	Tennessee	114
New Hampshire	24	Texas	520
New Jersey	98	Utah	5
New Mexico	44		
New York	231	Vermont	33
North Carolina	168	Virginia	54
North Dakota	49	Washington	154
Ohio	250	West Virginia	18
Oklahoma	94	Wisconsin	136
Oregon	63	Puerto Rico	15
Pennsylvania	415		

Canadian Provinces

Alberta	41
British Columbia	37
Manitoba	68
Ontario	93
Quebec	254
Saskatchewan	1

- Tamoxifen (trade name Nolvadex®) was proven in the BCPT to reduce breast cancer incidence by 49 percent in women at increased risk of the disease. The FDA approved the use of tamoxifen to reduce the incidence of breast cancer in women at increased risk of the disease in October 1998. Tamoxifen has been approved by the FDA to treat women with breast cancer for more than 20 years and has been in clinical trials for about 30 years.
- Raloxifene (trade name Evista®) was shown to reduce the incidence of breast cancer in a large study of its use to prevent and treat osteoporosis. This drug was approved by the FDA to prevent osteoporosis in postmenopausal women in December 1997 and to treat osteoporosis in postmenopausal women in September 1999. It has been under study for about seven years.

Contact Information

- Postmenopausal women in the United States and Puerto Rico who are interested in participating in STAR can call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for information in English or Spanish. The number for callers with TTY equipment is 1-800-332-8615.

- Postmenopausal women in Canada who are interested in participating in STAR can call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333 for information in English or French.
- For more information via the Internet, visit NSABP's Web site at **<http://www.nsabp.pitt.edu>** or NCI's clinical trials Web site at **<http://cancertrials.nci.nih.gov>**.

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For more information about cancer, visit NCI's Web site at <http://www.cancer.gov>.