



FOR IMMEDIATE RELEASE

Thursday, July 27, 2000

National Institutes of
Health

NCI Press Office
(301) 496-6641

NSABP Operations Center
(412) 330-4621

STAR Enrolls 6,139 Women in First Year; Participation of African-Americans Gaining Momentum

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 which began July 1, 1999. 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. Of them, 3,786 were African-American, a number that reflects an increase in awareness and interest in clinical trial participation since the first major breast cancer prevention trial.

Many of the total 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 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).

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

NSABP Chairman Norman Wolmark, M.D., said, “We are pleased that so many African-American women have joined this trial to help us answer this important medical question. We encourage all 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.”

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 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. Werta 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.”

Elizabeth Lee of Syracuse, New York represents African-American women as a member of the STAR Participant Advisory Board. Lee enrolled in the BCPT after being diagnosed with lobular carcinoma in-situ (LCIS), a noncancerous condition that increases risk of developing invasive breast cancer. For her, participating in a clinical trial was an option that provided access to state-of-the-art medical care and the opportunity to learn more about herself and breast cancer.

“It was the first time in a year that I felt a sense of hope, a means of being proactive as well as being empowered to help myself, my daughters, my six granddaughters and, hopefully, other women in my position,” said Lee.

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.

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.

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

- 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.
- 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).

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.
- For more information via the Internet (including a list of the number of women who joined STAR sorted by state), visit NSABP's Web site at <http://www.nsabp.pitt.edu> or NCI's clinical trials Web site at <http://cancertrials.nci.nih.gov>.

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

###