

EMBARGOED FOR RELEASE
10 a.m. EDT
Tuesday, May 25, 1999

NCI Press Office
(301) 496-6641

NSABP Operations Center
(412) 330-4657

**Breast Cancer Prevention Study Seeks Volunteers:
Study of Tamoxifen and Raloxifene (STAR) Under Way Across North America**

The Study of Tamoxifen and Raloxifene, or STAR, one of the largest breast cancer prevention studies ever, is now recruiting volunteers at more than 400 centers across the United States, Puerto Rico, and Canada. The trial will include 22,000 postmenopausal women at increased risk of breast cancer to determine whether the osteoporosis prevention drug raloxifene (Evista®) is as effective in reducing the chance of developing breast cancer as tamoxifen (Nolvadex®) has proven to be.

STAR is a study of the National Surgical Adjuvant Breast and Bowel Project (NSABP), a network of research professionals, and is supported by the National Cancer Institute (NCI).

“Studies of raloxifene suggest it has the potential to prevent breast cancer,” said Norman Wolmark, M.D., NSABP chairman. “The only way to prove that potential is to do a clinical trial in which the risks and benefits of raloxifene are directly compared with the risks and benefits of tamoxifen.”

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 high risk of breast cancer. Results of this trial were announced a year ago (April 6, 1998) and published in the *Journal of the National Cancer Institute* on Sept. 16, 1998. In the BCPT, half the women took tamoxifen and half took a placebo (an inactive pill that looked like tamoxifen). Participants taking tamoxifen also had fewer fractures of the hip, wrist, and spine than

(more)

women taking the placebo. However, the drug increased the women's chances of developing four potentially life-threatening health problems: endometrial cancer (cancer of the lining of the uterus), deep vein thrombosis (blood clots in large veins), pulmonary embolism (blood clot in the lung), and possibly stroke. 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.

Leslie Ford, M.D., associate director for clinical research in NCI's Division of Cancer Prevention, noted that "tamoxifen is a medically proven intervention, but it is not perfect. Women who are at an increased risk of breast cancer need options for preventing this disease with a minimum of side effects, and STAR is a concerted effort to find one." Ford is responsible for all aspects of NCI's involvement in STAR.

Information about the safety of raloxifene is limited compared to the data available on tamoxifen. Raloxifene was approved in December 1997 by the FDA to prevent osteoporosis and has been in clinical trials for about five years. 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. Women taking raloxifene in studies of osteoporosis have had an increased chance of developing a deep vein thrombosis or pulmonary embolism similar to the risk seen with tamoxifen. In these studies, raloxifene did not increase the risk of endometrial cancer. An important part of STAR will be to compare the long-term safety of raloxifene and tamoxifen in women at increased risk for breast cancer.

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.

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

The maker of tamoxifen, Zeneca Pharmaceuticals, Wilmington, Del., and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Ind., are providing their drugs for the trial

(more)

without charge. Eli Lilly and Company has also given NSABP a \$36 million grant to defray recruitment costs at the participating centers and to help local investigators conduct the study.

For more information about STAR and a list of participating centers:

- C In the United States (including Puerto Rico), call the National Cancer Institute'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.
- C In Canada, call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333 for information in English or French.
- C Visit NSABP's Web site at **<http://www.nsabp.pitt.edu>** or NCI's clinical trials Web site at **<http://cancertrials.nci.nih.gov>**

#