

PRESS RELEASE:

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Breast Cancer Prevention Study Confirms Effectiveness of Two Drugs

(Hendersonville, N.C.) The Comprehensive Cancer Center at Pardee has learned of an update on the results of the study of raloxifene and tamoxifen, (STAR P-2 trial in breast cancer prevention). The study shows that the drug raloxifene (initially used to prevent and treat osteoporosis in postmenopausal women) improved its effectiveness against noninvasive breast cancer, caused significantly less endometrial cancer and was significantly less toxic than tamoxifen. After 81 months of follow-up, although raloxifene was slightly less effective against invasive breast cancer, it still maintained strong efficacy.

The Comprehensive Cancer Center at Pardee Hospital participated in the STAR Study, one of the largest breast cancer prevention clinical trials ever conducted. STAR enrolled 19,490 postmenopausal women who were at increased risk for the disease in the follow-up study. At Pardee, 43 women were enrolled and in North Carolina, 915 women were enrolled.

This long-term trial is coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP), a network of cancer research professionals, and is sponsored by the National Cancer Institute, part of the National Institutes of Health.



Participants were randomly assigned to receive either 60 mg of raloxifene (Evista®) (9,754 participants) or 20 mg of tamoxifen (Nolvadex®) (9,736 participants) daily. The 81-month study results (versus the 47 months in the initially published report) show that raloxifene retained 76% of the effectiveness in preventing invasive disease and grew closer to tamoxifen in preventing noninvasive disease, while remaining less toxic. The relative effects of the drugs in the longer term are more consistent with expected profiles, including greater potency of tamoxifen in preventing invasive and noninvasive disease, and significantly less endometrial toxicity with raloxifene.

“These results help clarify that both raloxifene and tamoxifen are good preventive choices for high risk postmenopausal women depending largely on a woman’s risk factors,” said Norman Wolmark, M.D., NSABP Chairman. “The results of this longer-term study should encourage wide spread acceptance of raloxifene and greater acceptance of tamoxifen for breast cancer prevention among postmenopausal women at an elevated risk, ultimately reducing the burden of breast cancer on the public health.”

STAR participants were postmenopausal, at least 35-years old, and had a modified breast cancer risk as determined by their age, family history of breast cancer,



personal medical history, age of first menstrual period, and age at first live birth.

Eligible women were randomly assigned to receive either tamoxifen or raloxifene daily for five years. Before participating in the Study, women were instructed about the potential risks and benefits of tamoxifen and raloxifene, and then were asked to sign an informed consent document.

The makers of tamoxifen, AstraZeneca Pharmaceuticals, Wilmington, Delaware, and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Indiana, provided their drugs and matching placebos for the trial without charge to participants. Eli Lilly and Company, also, gave NSABP support to defray recruitment costs at the participating centers and to help local investigators conduct the study.

[Pardee Hospital](http://www.pardeehospital.org) is a not-for-profit community hospital founded in 1953. The main hospital is licensed for 222 acute care beds and is the second largest employer in Henderson County. The hospital has several locations separate from the main campus, including an adult day services center, a health education center in the Blue Ridge Mall, home care services, a rehab and wellness center, a midwifery program, various family and internal medicine practices, and an urgent care facility. For more information or to find a physician, call 1-866-790-WELL (9355) or visit www.pardeehospital.org.

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