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Early study analysis suggests exemestane reduces breast density in high risk postmenopausal women

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A drug that shows promise for preventing breast cancer in postmenopausal women with an increased risk of developing the disease, appears to reduce mammographic breast density in the same group of women. Having dense breast tissue on mammogram is believed to be one of the strongest predictors of breast cancer. The preliminary analysis from the small, phase II study was presented today at the 33rd Annual CTRC-AACR San Antonio Breast Cancer Symposium in Texas.

The ongoing study at Georgetown Lombardi Comprehensive Cancer Center and the Center for Cancer Research at the National Cancer Institute examines the effect of exemestane (Aromasin®) on breast density. Exemestane is in a class of medications called aromatase inhibitors (AI). It works by decreasing the amount of estrogen produced by the body. This can slow or stop the growth of some breast tumors that need estrogen to grow.

In this study, a preliminary analysis was conducted for the first 23 participants enrolled (42 women were enrolled as of June 2010). Mammograms were taken before the women began exemestane and one year after treatment started. Breast density was compared between the two mammograms for each woman.

"Overall, we saw a seven percent decrease in mammographic density among the women, a statistically significant finding," says Jennifer Eng-

Wong, M.D., M.P.H., assistant professor of oncology at Lombardi Comprehensive Cancer Center, a part of Georgetown University Medical Center. "Previous studies with AIs in high risk women have not shown a significant decline in mammographic density and differences in results may be due to duration of treatment or baseline characteristics of the study population."

She says earlier studies with tamoxifen, an FDA-approved drug to reduce breast cancer risk in women at high risk, also reduced breast density. A change in breast density appears to be an intermediate marker for breast cancer. For example a 10 percent drop in breast density was correlated with a 50 percent drop in breast cancer incidence. Tamoxifen is in a different class of drugs. Side-effects of taking it have deterred women from choosing tamoxifen, resulting in a need for other treatment options such as aromatase inhibitors. In general, both of these agents are well tolerated, however rare serious side effects of tamoxifen include thrombo-embolic disease and endometrial cancer. The AIs are not associated with these side effects but have been associated with an increased risk of bone fracture and loss of bone density.

Women who were eligible for the study had an increased risk of breast cancer defined as one of the following: five year Gail model of risk ≥1.7 percent, a high risk breast lesion (e.g. lobular neoplasia or ductal carcinoma in situ), a known BRCA1/2 mutation, or a prior stage I/II breast cancer with treatment completed two years prior to enrolling in the study. Women were excluded if testing revealed osteoporosis.

Eng-Wong points out that this stage of the analysis does not include a control group (women not taking exemestane) with whom the current findings could be compared, but she says a matched control comparison is planned. The study will continue until an analysis can be conducted on mammographic density after two years of treatment.