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Initial Results of the Study of Tamoxifen and Raloxifene (STAR) Released: Osteoporosis Drug Raloxifene Shown to be as Effective as Tamoxifen in Preventing Invasive Breast Cancer

Initial results of the Study of Tamoxifen and Raloxifene, or STAR, show that the drug raloxifene, currently used to prevent and treat osteoporosis in postmenopausal women, works as well as tamoxifen in reducing breast cancer risk for postmenopausal women at increased risk of the disease. In STAR, both drugs reduced the risk of developing invasive breast cancer by about 50 percent. In addition, within the study, women who were prospectively and randomly assigned to take raloxifene daily, and who were followed for an average of about four years, had 36 percent fewer uterine cancers and 29 percent fewer blood clots than the women who were assigned to take tamoxifen. Uterine cancers, especially endometrial cancers, are a rare but serious side effect of tamoxifen. Both tamoxifen and raloxifene are known to increase a woman's risk of blood clots.

STAR, one of the largest breast cancer prevention clinical trials ever conducted, enrolled 19,747 postmenopausal women who were at increased risk of the disease. Participants were randomly assigned to receive either 60 mg of raloxifene (Evista®) or 20 mg of tamoxifen (Nolvadex®) daily for five years. The 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 (NCI), part of the National Institutes of Health.

"This optimistic news from STAR is a significant step in breast cancer prevention," said John E. Niederhuber, M.D., currently providing leadership at NCI. "These results, once again, demonstrate the critical importance of clinical trials in our efforts to establish evidence-based practices."

"In 1998, the landmark Breast Cancer Prevention Trial showed that tamoxifen could reduce the risk of invasive breast cancer in premenopausal and postmenopausal women by nearly 50 percent," said Norman Wolmark, M.D., NSABP chairman. "Today, we can tell you that for

(more)

postmenopausal women at increased risk of breast cancer, raloxifene is just as effective, without some of the serious side effects known to occur with tamoxifen."

Women taking either drug had equivalent numbers of strokes, heart attacks, and bone fractures. Both raloxifene and tamoxifen are known to protect bone health; it is estimated that half a million postmenopausal women are currently taking raloxifene by prescription to prevent or treat osteoporosis. Additionally, the initial results from STAR suggest that raloxifene does not increase the risk of developing a cataract, as tamoxifen does.

“Although no drugs are without side effects, tamoxifen and raloxifene are vital options for women who are at increased risk of breast cancer and want to take action,” said Leslie Ford, M.D., associate director for clinical research in NCI’s Division of Cancer Prevention. “For many women, raloxifene’s benefits will outweigh its risks in a way that tamoxifen’s benefits do not.”

The STAR researchers also tracked known menopausal side effects that occur with both drugs and monitored the participants’ quality of life. The data show that side effects of both drugs were mild to moderate in severity, and quality of life was the same for both drugs.

Participants in STAR are now receiving information about which drug they were taking. Women assigned to raloxifene will continue to be provided with the drug until they have completed five years of treatment. Those women assigned to tamoxifen can choose to continue taking tamoxifen or to receive raloxifene to complete their five years of treatment.

Study details include:

- STAR enrolled 19,747 women. This data analysis is based on the 19,471 women for whom complete study information was available.

- The numbers of invasive breast cancers in both groups of women were statistically equivalent. Among the 9,745 women in the raloxifene group, 167 developed invasive breast cancer, compared to 163 of 9,726 women in the tamoxifen group.

- More than half of the women who joined STAR had had a hysterectomy and, therefore, were not at risk of uterine cancer. For those women with a uterus, 36 of 4,732 who were assigned to take tamoxifen developed uterine cancers (mainly endometrial cancer) compared to 23 of 4,712 women who were assigned to take raloxifene.

- In STAR, women in the raloxifene group had 29 percent fewer deep vein thromboses (blood clots in a major vein) and pulmonary embolisms (blood clots in the lung) than women in the tamoxifen group. Specifically, 87 of 9,726 women in the tamoxifen group had a deep vein thrombosis compared to 65 of 9,745 women taking raloxifene. In addition, 54 of 9,726 women taking tamoxifen developed pulmonary embolisms compared to 35 of 9,745 women taking raloxifene.

- The number of strokes occurring in both groups of women was statistically equivalent: 53 of 9,726 women in the tamoxifen group and 51 of 9,745 women in the raloxifene group had a stroke during the trial. There was no difference in deaths from strokes: 6 of 9,726 women in the tamoxifen group and 4 of 9,745 women in the raloxifene group died from this event. Women at increased risk of stroke (those with uncontrolled hypertension or uncontrolled diabetes, or a history of stroke, transient ischemic attack, or atrial fibrillation) were not eligible to participate in STAR.

- While tamoxifen has been shown to reduce, by half, the incidence of lobular carcinoma in situ (LCIS) and ductal carcinoma in situ (DCIS), raloxifene did not have an effect on these diagnoses. (LCIS and DCIS are sometimes called noninvasive breast cancers.) Of the 9,726 women taking tamoxifen, 57 developed LCIS or DCIS, compared to 81 of 9,745 taking raloxifene. This result confirms data reported in 2004 in a large study of raloxifene, the Continued Outcomes Relevant to Evista (or CORE Trial).

Women who participated in STAR were postmenopausal, at least 35 years old, and had 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. Before participating in the study, the women were instructed about the potential risks and benefits of tamoxifen and raloxifene and then were asked to sign an informed consent document.

STAR investigators will present additional data at the 42nd annual meeting of the American Society for Clinical Oncology (ASCO) from June 2-6, 2006, in Atlanta, Ga. "This is an important and long awaited trial," said Sandra J. Horning, M.D., president of ASCO, "and we look forward to further discussion and analysis at the ASCO annual meeting that will address the observed differences in toxicity and prevention of non-invasive breast cancers with the two treatment approaches." A manuscript is also being submitted to a peer-reviewed journal for publication.

The maker of tamoxifen, AstraZeneca Pharmaceuticals, Wilmington, Del., and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Ind., 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.

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For more information about STAR, including links to media materials and a fact sheet, visit NCI's STAR home page at http://www.cancer.gov/star or at NSABP's Web sites at http://www.nsabp.pitt.edu or http://foundation.nsabp.org.

For a Q&A related to the STAR results, go to:
http://www.cancer.gov/newscenter/pressreleases/STARresultsQandA.

For B-roll related to the STAR results, go to www.thenewsmarket.com for digitized, downloadable B-roll, or call the NCI Media Relations Branch at (301) 496-6641 for a Beta-tape copy.

For tools used to calculate a woman's risk of breast cancer, visit http://cancer.gov/bcrisktool or http://breastcancerprevention.com.