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UB played major role in study on drug that reduces breast cancer in high-risk women

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Today's major announcement at the American Society of Clinical Oncology annual meeting that the drug exemestane significantly reduces the risk of breast cancer in high-risk, postmenopausal women is the result of an international, randomized double-blind phase III clinical trial in which University at Buffalo researchers and hundreds of Western New York women played a critical role.

The findings will be published online June 4 at 11:30 a.m. EST in the *New England Journal of Medicine*.

More than 500 Western New York women participated in the study, according to Jean Wactawski-Wende, PhD, principal investigator of the Buffalo ExCel clinical center, co-author of the manuscript and professor and associate chair of the Department of Social and Preventive Medicine in the UB School of Public Health and Health Professions.

In all, 4,560 women participated at sites located throughout the U.S., Canada, France and Spain.

"Our center here in Western New York had the largest enrollment of any site involved in the exemestane study, including those based in major cities much larger than Buffalo," says Wactawski-Wende, also a professor in the Department of Gynecology-Obstetrics in the UB School of Medicine and Biomedical Sciences and UB vice provost for strategic initiatives.

That didn't surprise her. As a researcher on numerous clinical research studies, some of which were part of the landmark Women's Health Initiative, a national study launched in 1993 by the National Institutes of Health to address women's health, Wactawski-Wende has found Western New York women particularly eager to participate.

"We have been so successful here in Western New York in enrolling women in clinical trials," she says. "Western New York women are particularly willing to do their part to advance knowledge and advance science. They do it for their daughters and their granddaughters. They're so altruistic. They want to know more about how to improve women's health and prevent diseases like cancer. My observation is that they join these studies not to help themselves but to help someone else. These women are really stepping up to the plate to advance scientific knowledge."

Study participants will be learning about the results when they are released on June 5. Over the next few months, participants will be coming to the clinical centers to close out their participation.

Media interested in speaking with participants should submit requests to goldbaum@buffalo.edu; requests will be addressed beginning on June 6.

The MAP.3 (Mammary Prevention Trial-.3), as it is called, was led by Canada's NCIC Clinical Trials Group. Participants knew the study as "ExCel," referring to the use of exemestane as the active medication being tested.

The study showed that in postmenopausal women at increased risk of breast cancer, but who have not previously been diagnosed with breast cancer, the aromatase inhibitor called Aromasin, made by Pfizer, reduces this risk by 65 percent compared with placebo.

The study also found that "no serious toxicities and only minimal changes in health-related quality of life" occurred in women taking exemestane, according to the NEJM paper.

"These are very exciting results," says Wactawski-Wende. "There were very few side effects and limited adverse events. Exemestane is already being used in thousands of women who already have breast cancer to prevent a recurrence, so we expect it will be generally acceptable for use in women at high risk who want to reduce their chances of developing breast cancer in the first place."

She notes that the fact that throughout the average, three-year-followup period, women tolerated exemestane very well and experienced few adverse events is especially positive, given the fact that the two medications currently approved for preventing breast cancer, tamoxifen and raloxifene, are not widely used, in part because they are not well-tolerated in some women.

While tamoxifen and raloxifene are selective, estrogen-receptor modulators (anti-estrogens), exemestane, an aromatase inhibitor, works through a different mechanism.

According to the NEJM paper, aromatase inhibitors "profoundly suppress estrogens in postmenopausal women." They also are known to be superior to tamoxifen in preventing recurrences in patients with early breast cancer, a factor that led the investigators to undertake the current trial to see if it could prevent breast cancer in high-risk, healthy women.

This is the first randomized trial to evaluate an aromatase inhibitor as a breast cancer preventative agent in healthy women.

The results show that exemestane cut the risk of cancer for these higher-risk, postmenopausal women by about two-thirds. Among those who

took exemestane, 11 women developed breast cancer as opposed to 32 women in the placebo group. According to Wactawski-Wende, that translates to an annualized incidence of 19 women per 10,000 who developed cancer while taking exemestane as opposed to 55 women per 10,000 in the group taking placebo.

More information: DOI: 10.1056/NEJMoa1103507

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