

## Hormone-blocking drug reduces breast cancer risk

June 4 2011, By MARILYNN MARCHIONE, AP Medical Writer

(AP) -- Millions of women at higher-than-usual risk of breast cancer have a new option for preventing the disease. Pfizer Inc.'s Aromasin cut the risk of developing breast cancer by more than half, without the side effects that have curbed enthusiasm for other prevention drugs, a major study found.

It was the first test in healthy women of newer hormone-blocking pills called aromatase inhibitors, sold as Arimidex, Femara and Aromasin, and in generic form. They're used now to prevent recurrences in breast cancer patients who are past menopause, and doctors have long suspected they may help prevent initial cases, too.

Prevention drugs aren't advised for women at average risk of breast cancer. Those at higher risk because of gene mutations or other reasons already have two choices for prevention - tamoxifen and <u>raloxifene</u>. But these drugs are unpopular because they carry small risks of uterine cancer, blood clots and other problems.

"Here's a third breast cancer prevention drug that may in fact be safer," said Dr. Allen Lichter, chief executive of the American Society of Clinical Oncology.

The study was discussed Saturday at the society's annual meeting in Chicago, along with another one that could change care for thousands of women each year with breast cancer that has spread to lymph nodes. It found that giving radiation to the armpit - not just the breast - after



surgery significantly lowered the chances the cancer would come back.

The prevention study involved 4,560 women from the U.S., Canada, Spain and France. They had at least one risk factor - being 60 or older, a prior breast abnormality or pre-invasive cancer, or a high score on a scale that takes into account family history and other things.

They were given daily doses of exemestane, sold as Aromasin, or dummy pills. After about three years, there were 11 cases of <u>invasive</u> <u>breast cancer</u> among those on the drug versus 32 among the others. That worked out to a 65 percent reduction in risk for those on the drug - enough of a benefit that independent monitors decided all participants should be offered it.

Serious side effects, such as broken bones, high cholesterol and heart problems, were similar in both groups. Slightly more women on the drug reported hot flashes, fatigue, sweating, insomnia and joint pain, but quality-of-life scores were similar.

Earlier studies of aromatase inhibitors found they can cause bone loss, vaginal dryness, problems having sex, joint pain and muscle aches, so it will take longer study to see if these occur, Lichter said.

The study's leader, Dr. Paul Goss of Massachusetts General Hospital, figured that 26 women would need to take exemestane for five years to prevent a single case of breast cancer. Even though this study did not compare the drug to tamoxifen, previous studies suggested 96 women would need to take it for five years for each breast cancer prevented.

"This is a new option for prevention of invasive breast cancer for a wide pool of women," without the serious side effects of tamoxifen or raloxifene, Goss said.



Results were published online by the New England Journal of Medicine. The Canadian Cancer Society, Pfizer and the Avon Foundation helped pay for the study. Goss and some other researchers have been paid speakers for Pfizer and other cancer drug makers.

Brand-name aromatase inhibitors cost \$340 to \$420 a month, although some are available as generics. Aromasin's U.S. patent expired in April and will expire in Europe and Japan in July.

A second study at the conference focused on treating breast cancer that has spread to the lymph nodes. Standard treatment is surgery followed by chemotherapy or hormone therapy and several weeks of radiation to the breast. Women with large tumors or many cancerous nodes also get radiation to the armpit and lower neck, but doctors don't know if this helps women with smaller tumors or only one to three cancerous nodes - a common situation.

Dr. Timothy Whelan of McMaster University in Hamilton, Ontario, Canada, led a study of 1,832 such women. All received standard treatment with radiation to the breast, and half also had radiation in the armpit and lower neck area.

After about five years, 90 percent of those given wider radiation were cancer-free versus 84 percent of the others, and there was a trend toward better survival with more radiation.

Lung inflammation and lymphedema - painful arm swelling caused by poor drainage - were more common with wider radiation, but doctors said these side effects were worth the benefit of fewer cancer recurrences.

The results are "potentially practice-changing" and will encourage doctors to offer wider radiation, Whelan said.



Worldwide, about 1.3 million women are diagnosed with breast cancer each year and nearly 500,000 women die of the disease. Last year in the United States, there were about 207,000 new cases and 40,000 deaths from breast cancer.

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Online:

Breast cancer: http://bit.ly/iIrUxt

Breast cancer risk calculator: http://cancer.gov/bcrisktool

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Marilynn Marchione can be followed at <a href="http://twitter.com/MMarchioneAP">http://twitter.com/MMarchioneAP</a>

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