

Women With Dense Breasts Are at Higher Risk for Cancer

The Associated Press

Atossa Genetics, Inc. (NASDAQ: ATOS) announced that its new ForeCYTE Breast Health System addresses the problem of detecting not only cancer, but also the early cellular changes that lead to cancer, in women with dense breasts.

Numerous studies have shown that women with denser breast tissue, and thus more gland tissue and less fatty tissue, are at higher risk for breast cancer. Moreover, as the American Cancer Society (ACS) explains, "Dense breast tissue can also make it harder for doctors to spot problems on mammograms." (ACS Guidelines.)

This is why five states -- California, Texas, New York, Connecticut and Virginia -- have passed legislation requiring that women whose mammograms show dense breasts must be notified of this fact, and several other states and the U.S. Congress are considering such legislation. For instance, the New York law, which took effect January 19, 2013, states that mammography patients with dense breasts must be told: "Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue can make it harder to find cancer on a mammogram and may also be associated with an increased risk of breast cancer."

One key study highlights those risks. Scientists at the University of California, San Francisco examined aspirated fluid from the breasts of 2,700 women between the ages of 25 to 65. This fluid contains duct cells, which are responsible for more than 90 percent of breast cancers. The study found that women with dense breasts were more than four times more likely than women without dense breasts to have a condition called atypical hyperplasia -- in which the cells seem to grow too quickly and pile up on each other. These atypical cells represent the first steps on the path to cancer. As a result, spotting these cells is not only key to detecting the risk of cancer in these women; it also opens the door to treating the condition and halting the progression to cancer.

"It is vital that we understand the limits of mammography and give women a better test -- one that is capable of detecting the earliest signs of precancer," said Steven C. Quay, M.D., Ph.D., FCAP, Atossa Genetics' Chairman of the Board and Chief Executive Officer.

In January, Atossa Genetics launched such a diagnostic: the ForeCYTE Breast Health Test. The test, cleared by the U.S. Food & Drug Administration, uses a breast pump called the Mammary Aspirate Specimen Cytology Test (MASCT) to painlessly collect miniscule amounts of fluid from the milk ducts in women's breasts, analyzes the duct cells for hyperplasia and other abnormalities, and analyzes for genetic

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mutations.

In essence, this test is like a Pap smear for cancer, spotting the earliest cellular warnings up to eight years before cancer can be detected by any other method. Women with dense breasts, therefore, could be monitored every year or so for signs of atypical hyperplasia. As long as the results come back negative, these women could lead normal lives without fear of cancer. But if hyperplasia is detected, women could be treated to reverse the condition.

"Just as Pap smears have reduced cervical cancer rates by over 75 percent, becoming the most successful screening test in medicine, this test can detect the precursor changes that lead to breast cancer -- and make prevention possible," says Quay. "We believe this test should be mandatory for women with dense breasts."

To use Atossa's ForeCYTE Breast Health System, see your doctor. The Atossa test is being distributed to health care providers nationwide by Clarity Women's Health (a division of Diagnostic Test Group, LLC) of Boca Raton, Florida. (See press release.)

For background and additional information on breast density legislation, see WSJ online.

About Atossa Genetics, Inc. Atossa Genetics, Inc. (NASDAQ: ATOS), The Breast Health Company, is based in Seattle, Washington, and is focused on preventing breast cancer through the commercialization of patented, FDA-cleared diagnostic medical devices and patented, laboratory developed tests (LDT) that can detect precursors to breast cancer up to eight years before mammography, and through research and development that will permit it to commercialize treatments for pre-cancerous lesions.

The National Reference Laboratory for Breast Health (NRLBH), a wholly owned subsidiary of Atossa Genetics, Inc., is a CLIA-certified high-complexity molecular diagnostic laboratory located in Seattle, WA, that provides the patented ForeCYTE Breast Health Test, a risk assessment test for women 18 to 73 years of age akin to the Pap smear, and the ArgusCYTE Breast Health Test, a blood test for recurrence in breast cancer survivors that provides a "liquid biopsy" for circulating cancer cells and a tailored treatment plan for patients and their caregivers.

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