



# Health Awareness

## Know Your Breast Cancer Status Through Proper Diagnosis—Get Targeted Treatment

(NAPSA)—According to the American Cancer Society, approximately 211,000 women in the United States will be diagnosed with invasive breast cancer this year.

Up to 25 percent of women with breast cancer have a particularly aggressive form of the disease called HER2-positive breast cancer. This means they have extra copies of the HER2 gene, causing tumors to produce too many HER2 protein receptors, which trigger cancer cells to multiply and grow more quickly than normal cells. Research has shown that this form spreads faster than HER2-negative breast cancer, is more likely to recur after chemotherapy, is associated with a decreased chance of survival and may not respond as well to standard therapies.

A drug developed specifically for HER2-positive breast cancer, Herceptin®, targets the HER2 receptor and, by binding to the HER2 receptors, is thought to prevent further tumor growth by interrupting the growth signal and may therefore slow the progress of the disease. Until recently, this treatment has only been used in women whose cancer has spread from the breast to other parts of the body, but new research indicates it may also work in HER2 positive patients when used earlier in the disease immediately following surgery.

Two large clinical trials completed in May of 2005 showed a 52 percent decrease in recurring tumors for early-stage patients who received Herceptin in addition to chemotherapy. This significant improvement may mean that more women will be able to use this treatment.

Treatments like Herceptin are part of an emerging era of personalized medicine that offers therapies

customized not only to a specific disease but to the patient herself. This level of personalization, in the case of HER2, is only made possible by the accurate detection of a woman's HER2 status.

For Herceptin to work, a woman must first be definitively diagnosed with HER2-positive breast cancer. For women diagnosed with breast cancer, knowing HER2 status is one of the most important factors for deciding treatment options, and they need to be sure that the test is accurate.

Fluorescence in situ hybridization (FISH) is a gene-based test that measures the number of HER2 genes in a cell. The test lights up the HER2 genes inside the cell like a Christmas tree, making them appear fluorescent so a doctor can count them accurately. If a patient has more than two genes per cell, she is considered HER2 positive. If the test shows a normal gene count, she is considered HER2 negative. Since FISH allows the doctor to literally count the genes, the test is more precise than other HER2 test methods.

“Over the past few years we've heard a lot about the promise of personalized medicine as it relates to innovative targeted treatments,” says Mark Pegram, M.D., Ph.D., director of the JCCC Women's Cancers Program Area at The University of California, Los Angeles. “While significant strides have been made in the therapeutic area it's important to recognize the role that diagnostic tests like FISH play in making sure women with breast cancer receive the best treatment based on their tumor's genetic profile.”

Breast cancer survivor Donna Henagin is an example of personalized medicine at its best. In April

2001, Donna was diagnosed with breast cancer and underwent surgery, having 37 lymph nodes removed. Testing with PathVysion®, a FISH test from Abbott Molecular, confirmed that Donna's cancer was HER2-positive. Based on the results, Donna's doctor recommended that she participate in a study for Herceptin treatment. Today, Donna is cancer-free and back at work as a heavy machinery operator.

“The PathVysion test helped my doctor positively identify me as a candidate for Herceptin as an experimental treatment,” Henagin said. “It helped my doctors make sure I got a medicine that worked for me and my cancer. Knowing my HER2 status made me feel much more comfortable about my decision to enter a trial for HER2 therapy.”

In recent years breast cancer deaths have declined as a result of earlier detection and improved treatments with fewer side effects. Gene-based diagnostic tests like PathVysion provide another crucial tool for physicians to better manage disease.

Women who want to get more information about breast cancer or need help understanding pathology results can log on to the Y-ME National Breast Cancer Organization's Web site at [www.y-me.org](http://www.y-me.org) for resources in their area. For more information about HER2 testing, talk to your doctor or visit [www.pathvysion.com](http://www.pathvysion.com).

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*Note to Editors: **Warning:** The Vysis PathVysion Kit is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients. In making decisions regarding adjuvant CAF treatment, all other available clinical information should also be taken into consideration, such as tumor size, number of involved lymph nodes, and steroid receptor status. No treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu gene amplification status alone.*

*Donna Henagin's comments related to PathVysion are not intended to represent the experience of all patients tested for the HER2 gene.*