



Genomic Health Announces Publication of Data Demonstrating that the Oncotype DX(R) Breast Cancer Test Significantly Influences Breast Cancer Treatment Decisions, While Increasing Physician Confidence and Patient Satisfaction

-- Separate Study Demonstrates Oncotype DX is a Significant Predictor of Local and Regional Recurrence of Breast Cancer Independent of Age, Tumor Size and Grade -- -- Both Studies and Supportive Editorial Published Online in the Journal of Clinical Oncology --

REDWOOD CITY, Calif., Jan 12, 2010 /PRNewswire via COMTEX News Network/ -- [Genomic Health, Inc.](#) (Nasdaq: GHDX) today announced the publication of a prospective, multi-center, study that showed the [Oncotype DX\(R\)](#) breast cancer test [Recurrence Score\(R\)](#) had a significant impact on [breast cancer](#) treatment decisions for early-stage breast cancer patients while increasing patient satisfaction and physician confidence in those decisions. The study found that knowledge of a patient's Recurrence Score changed oncologists' treatment recommendations in 31.5 percent of cases and changed 27 percent of [breast cancer](#) patients' treatment decisions. The study was published online on Monday in the *Journal of Clinical Oncology*.

The [Oncotype DX breast cancer test](#) measures the expression of 21 genes of an individual tumor to generate a [Recurrence Score](#) result that quantifies the magnitude of chemotherapy benefit and the likelihood of recurrence for early-stage breast cancer patients. As of November, more than 8,000 physicians have used the [Oncotype DX](#) test in more than 120,000 breast cancer patients.

"This is the first study to show that tests such as this simultaneously impact breast cancer treatment decisions by patients as well as physicians," said Shelly S. Lo, M.D., Assistant Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Loyola University Chicago Stritch School of Medicine, Cardinal Bernardin Cancer Center, Loyola University Health System, Maywood, Ill, and lead author of the study on *Oncotype DX*.

The study evaluated 89 [breast cancer](#) patients treated by 17 medical oncologists from three academic centers and one community practice. The most common change in treatment plan occurred among [breast cancer](#) patients who received a low Recurrence Score result - switching from an initial pre-Recurrence Score plan of chemotherapy plus hormonal therapy, to a treatment plan of hormonal therapy alone.

"There are additional factors in a tumor that drive its biologic behavior that we cannot identify from a good pathology report alone," said Kathy S. Albain M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Loyola University Chicago Stritch School of Medicine, Cardinal Bernardin Cancer Center, Loyola University Health System, Maywood, Ill, and senior author of the study. "By knowing the [Oncotype DX Recurrence Score](#), we can often avoid giving chemotherapy to patients we previously thought needed it, while offering chemotherapy with confidence to those for whom there was no indication for it based on traditional pathologic measures."

Researchers also assessed physicians' and patients' experience in using the [Oncotype DX](#) breast cancer test and the impact it had on their confidence levels about breast cancer treatment decisions. The study found that in 76 percent of the cases, oncologists reported increased confidence in their treatment decision. Additionally, 95 percent of patients said that they were glad they received a [Recurrence Score](#) result to individualize their treatment, and 83 percent of patients felt the *Oncotype DX* breast cancer test influenced their treatment choice, regardless of whether it changed or reinforced their original decision.

"As more physicians incorporate diagnostic tools such as *Oncotype DX* into clinical practice, it is critical to evaluate how that molecular information impacts treatment selection," said [Steven Shak, M.D.](#), chief medical officer of Genomic Health. "There are now five studies, which have been presented or published, establishing that, on average, breast cancer treatment recommendations change 30 percent of the time when the [Oncotype DX Recurrence Score](#) is available."

A separate study, also published online on Monday in the *Journal of Clinical Oncology*, demonstrated that the *Oncotype DX* Recurrence Score, which quantifies the risk of distant recurrence for a large portion of early-stage breast cancer patients, also significantly predicts local or regional recurrence, which is when breast cancer returns to the same or nearby remaining organ or tissue. This is the first study to show such an association based on a sizeable population of tamoxifen and chemotherapy-treated patients from randomized clinical trials.

"As with distant recurrence, our analysis confirms a significant association between a patient's Recurrence Score and time to

first local or regional recurrence independent of a patient's age, tumor size or tumor grade," said Terry Mamounas, M.D., chair of the NSABP Breast Committee, medical director, Aultman Cancer Center, Canton, Ohio, and lead author of the study. "These results have potential clinical implications for individualized loco-regional therapy decisions in patients with early-stage breast cancer and we look forward to exploring this correlation in additional breast cancer patient populations."

This analysis of 1,674 patients from previous [NSABP B-14 and B-20](#) randomized clinical trials (895 tamoxifen-treated patients, 355 placebo-treated patients and 424 chemotherapy plus tamoxifen-treated patients) demonstrated a clear association between the Recurrence Score results as identified by Oncotype DX and risk for loco-regional recurrence (LRR). Specifically, the study found the [Recurrence Score](#) to be a significant predictor of LRR among the 895 tamoxifen-treated patients with lymph node-negative (N-), estrogen receptor-positive (ER+) breast cancer (p-value < 0.001), independent of age, clinical tumor size and tumor grade. Significant associations of the Recurrence Score and LRR were also observed in the placebo-treated and chemotherapy plus tamoxifen-treated patients (p-value < 0.05).

About Oncotype DX^(R)

The Oncotype DX breast cancer test is the only multigene expression test commercially available that has clinical evidence validating its ability to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage breast cancer. Additionally, the test report provides quantitative scores for certain individual genes. The Oncotype DX breast cancer test has been extensively evaluated in thirteen clinical studies involving more than 4,000 breast cancer patients worldwide, including a large validation study published in *The New England Journal of Medicine* and a chemotherapy benefit study published in the *Journal of Clinical Oncology*. As of November 2009, more than 8,000 physicians have ordered more than 120,000 tests in over 50 countries, and both Medicare and private health plans covering over 90 percent of U.S. insured lives, provide reimbursement for Oncotype DX for patients with node-negative breast cancer that is estrogen-receptor positive and/or progesterone-receptor positive through contracts, agreements or policy decisions. Both the American Society of Clinical Oncology and the National Comprehensive Cancer Network recommend the use of Oncotype DX for patients with node-negative breast cancer that is estrogen-receptor positive and/or progesterone-receptor positive. For more information about Oncotype DX, please visit www.oncotypedx.com.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is a life science company focused on the development and commercialization of genomic-based clinical laboratory services for cancer that allow physicians and patients to make individualized treatment decisions. In 2004, Genomic Health launched the Oncotype DX^(R) breast cancer test, which has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage breast cancer. In addition to the widely adopted Oncotype DX breast cancer test, Genomic Health is preparing to launch its [Oncotype DX colon cancer](#) test in the first quarter of 2010. The company was founded in 2000 and is located in Redwood City, California. For more information, please visit www.genomichealth.com.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the applicability of clinical study results to actual outcomes, the potential benefits or implications in the clinical setting of using the company's test, and the company's plans to commercialize a test for colon cancer and the proposed timing of such commercialization. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the risks and potential delays associated with commercialization of a new test; the risks and uncertainties associated with the regulation of the company's tests; the applicability of clinical study results to actual outcomes; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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