



Genomic Health Announces Publication of Study of Oncotype DX(R) in Node-Positive Breast Cancer That Identifies Patients Who Do Not Appear to Benefit From Chemotherapy

- Study Results Published Early in *The Lancet Oncology* to Coincide with Late-Breaking Presentation of Additional Node-Positive Data at CTRC-AACR San Antonio Breast Cancer Symposium -

SAN ANTONIO, Dec 10, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced that *The Lancet Oncology* published positive results from a study of Oncotype DX((R)) in postmenopausal women with node-positive, estrogen receptor-positive breast cancer conducted by the Southwest Oncology Group (SWOG), a National Cancer Institute-supported clinical trials cooperative group. *The Lancet Oncology* published these results online as an "early release" to coincide with additional data analyses reinforcing that the Oncotype DX breast cancer test can help predict chemotherapy benefit in breast cancer patients with node-positive disease. These data, presented today as a late-breaking poster during a discussion on multigene assays at the 32nd Annual CTRC-AACR San Antonio Breast Cancer Symposium (Abstract #112), support the clinical utility of Oncotype DX in this patient population.

The study published in *The Lancet Oncology* challenges the current treatment standard of adjuvant chemotherapy for all women with lymph node-positive breast cancer.

"These studies indicate that the Oncotype DX Recurrence Score((R)) result can provide beneficial clinical information beyond standard pathology testing for node-positive breast cancer patients," 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, Il, and senior author of the study. "With the right chemotherapy regimen, we can favorably impact survival; but it is also important to avoid the toxicity and medical costs of chemotherapy when it may not be needed for patients whose tumors have a distinct biology not responsive to standard chemotherapy."

For the study published in *The Lancet Oncology*, researchers analyzed 367 tumor samples from node-positive, estrogen receptor-positive breast cancer patients who participated in the SWOG/Breast Cancer Intergroup of North America trial that evaluated CAF chemotherapy followed by tamoxifen versus tamoxifen-alone, to determine the prognostic and predictive effects of the Oncotype DX Recurrence Score.

The Recurrence Score was highly prognostic in the tamoxifen-alone arm ($p=0.006$) and demonstrated predictive ability in those patients treated with chemotherapy followed by tamoxifen. Specifically the study found no chemotherapy benefit in the low Recurrence Score group (log-rank $p=0.97$; HR=1.02); however, there was significant disease-free survival improvement for the high Recurrence Score group (log-rank $p=0.03$; HR=0.59).

"Since these data were originally presented in 2007, I have used Oncotype DX to help make treatment recommendations for select node-positive patients in my clinical practice," said Eric Winer, M.D., Chief, Division of Women's Cancers at Dana-Farber Cancer Institute and Professor of Medicine at Harvard Medical School. "It is imperative that we bring our new molecular insights into clinical practice so that we can optimize and individualize treatment for every patient with breast cancer."

Additional data analyses presented at the CTRC-AACR San Antonio Breast Cancer Symposium today reinforced the conclusion that chemotherapy does not appear to benefit patients with either 1-3 or 4 or more positive nodes for disease-free survival over 10 years, if their tumors have a low Recurrence Score. There was no breast cancer specific survival (BCSS) benefit from chemotherapy in either the low (log-rank $p=0.56$) or intermediate (log-rank $p=0.89$) Recurrence Score categories; however, chemotherapy resulted in superior BCSS in the high Recurrence Score category (log-rank $p=0.033$).

"There are now five studies involving more than 1,000 patients that support the clinical utility of Oncotype DX in guiding treatment selection for node-positive breast cancer," said Steven Shak, M.D., Chief Medical Officer, Genomic Health. "With this suite of clinical evidence, recently expanded Medicare coverage and clinical experience with more than 5,500 patients with node-positive breast cancer, we believe we can arm node-positive patients and their physicians with the same accurate, standardized genomic information that node-negative patients and their doctors have been using to help guide treatment plans over the past five years."

A separate study analyzing how the Oncotype DX Recurrence Score impacts treatment recommendations in breast cancer patients with node-positive disease (Abstract #2031) will be presented at the San Antonio Breast Cancer Symposium on Friday, December 11, 2009 at 7a.m. CST.

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 belief that the study data support the clinical utility in patients with node-positive disease, the belief that using Oncotype DX for breast cancer can avoid the toxicity and medical costs of chemotherapy when it may not be needed for certain patients, the importance of incorporating new molecular insights into clinical practice so that physicians can optimize and individualize treatment for patients with breast cancer, the company's belief that using Oncotype DX can provide node-positive patients and their physicians with the same accurate, standardized genomic information that node-negative patients and their doctors have been using to help guide treatment plans, the company's plans to commercialize a test for colon cancer and the proposed timing of such commercialization, and the applicability of clinical study results to actual outcomes. 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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