



## **Genomic Health Announces New Data Reinforcing Clinical Utility of Oncotype DX® in Multiple Breast Cancer Populations**

### **Studies Presented at the CTRC-AACR San Antonio Breast Cancer Symposium Provide Insights Into Treatment Impact for Node-Positive Patients; Demonstrate Potential Role of Oncotype DX in Neoadjuvant Treatment Planning**

REDWOOD CITY, CA, Dec 15, 2009 (MARKETWIRE via COMTEX News Network) -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results from five new studies on its Oncotype DX® breast cancer test, a multi-gene expression test that physicians currently use to predict the likelihood of chemotherapy benefit and recurrence risk for patients with early-stage breast cancer. These data were presented at the 32nd Annual CTRC-AACR San Antonio Breast Cancer Symposium, held December 9 - 13, 2009, in San Antonio, TX.

"The breadth of data presented at last week's meeting reflects our enduring commitment to provide physicians and their breast cancer patients with accurate and precise clinical information that can be used to make individualized treatment decisions," said Steven Shak, M.D., chief medical officer of Genomic Health. "We believe no other breast cancer test laboratory has demonstrated the reproducible clinical utility that Genomic Health has established with Oncotype DX, and we plan to continue to add value to the test through our ongoing research and clinical experience that includes more than 120,000 breast cancer patients."

Highlights from the five studies presented by Genomic Health and research collaborators include:

#### **Oncotype DX Predicts Anthracycline-Based Chemotherapy Benefit in Women with ER+, N+ Breast Cancer**

-- An analysis, presented as a late-breaking poster during a discussion on multigene assays on Thursday, December 10, 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(R) result. Researchers from Southwest Oncology Group (SWOG), a National Cancer Institute-supported clinical trials cooperative group, observed 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  $p=0.033$ ).

#### **Oncotype DX Leads to Fewer Recommendations of Chemotherapy for Women with Node-Positive Breast Cancer**

-- A multi-institutional clinical survey presented on Friday, December 11 involving 160 physicians who currently use Oncotype DX in node-positive breast cancer patients found that treatment recommendations frequently changed based on Recurrence Score results, with an overall reduction in chemotherapy treatment recommendations. In the 138 patients with node-positive, hormone receptor-positive breast cancer where the physician had a specific treatment recommendation before obtaining the Oncotype DX Recurrence Score, recommended treatment changed from hormonal therapy plus chemotherapy to hormonal therapy alone in 46 patients (33%), and from hormonal therapy alone to hormonal therapy plus chemotherapy in 13 patients (9%) after obtaining the Recurrence Score.

#### **Oncotype DX Can Be Successfully Performed on Breast Cancer Core Biopsy Samples, Suggesting Potential Role in Neoadjuvant Treatment Planning**

-- On Sunday, December 13, researchers presented results from a study examining pathology review and quantitative RT-PCR analysis by Oncotype DX on more than 11,000 core biopsy samples processed at the Genomic Health laboratory between July 15, 2005 and May 31, 2009. Physicians use core needle biopsies to obtain breast cancer tumor tissue without surgery for the purposes of diagnosis. Surgery, adjuvant, and neoadjuvant treatment decisions are based on the analysis of core needle biopsy tissue. The overall Oncotype DX success rate in core biopsy samples was greater than 97 percent, demonstrating that RT-PCR analysis by Oncotype DX can successfully be performed on core biopsies that have been fixed and paraffin-embedded.

Previous studies have shown the Recurrence Score result to be associated with the likelihood of response to neoadjuvant therapy(i)(ii)(iii). Patients with a higher Recurrence Score result had a greater chance of experiencing a response from neoadjuvant chemotherapy while patients with a lower Recurrence Score appeared to be more likely to achieve a response from endocrine therapy. Genomic Health plans to further assess the role of Oncotype DX in the neoadjuvant setting through a number of ongoing clinical trials.

#### **Exploratory Analysis of Gene Expression Identifies New Potential Therapeutic Targets, Biomarkers Associated with Recurrence**

-- In a study presented Saturday, December 12, researchers analyzed 371 genes and compared expression levels between hormone receptor-positive breast cancer cases and hormone receptor-negative cases. A number of the genes tested exhibited significantly higher expression in hormone receptor-positive breast cancer and pathway analysis showed substantial interconnectivity among these genes. The analysis further revealed several pathways that exhibit higher expression in hormone receptor-positive disease -- some of which were also associated with a higher risk of recurrence after chemohormonal therapy -- suggesting that they may be potential therapeutic targets and providing a rationale for evaluating both currently available and investigational agents that target these pathways.

#### **Oncotype DX and FISH Testing Both Detect Amplified HER2 Expression with Extra Copies of Chromosome 17**

-- On Sunday, December 13, Genomic Health researchers presented results of a large retrospective case-control study assessing the diagnosis of HER2 status, by both fluorescent in situ hybridization (FISH) testing and quantitative RT-PCR by Oncotype DX, to explore the association between polysomy 17 (extra copies of chromosome 17, a condition found in breast cancer patients that can complicate the interpretation of HER2 testing results), HER2 status and breast cancer death. Polysomy 17 was found in HER2-amplified tumors in approximately a third of cases. While differences were not statistically significant, HER2-positive patients with polysomy 17 tended to have a worse prognosis than other breast cancer patients. Quantitative RT-PCR by Oncotype DX for HER2 status is highly concordant with HER2 status assessed by FISH and therefore is an alternative to FISH.

**About Oncotype DX®** 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](http://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<sup>®</sup> 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](http://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 company's belief that the breadth of data presented reflects the company's commitment to provide physicians and their breast cancer patients with accurate and precise clinical information that can be used to make individualized treatment decisions, the company's belief that no other breast cancer test has demonstrated the reproducible clinical utility that Genomic Health has established with Oncotype DX, the company's plan to continue to add value to its breast cancer test through ongoing research and clinical experience, the belief that using Oncotype DX can predict chemotherapy benefit in women with ER+, N+ disease, the belief that Oncotype DX frequently changes treatment recommendations with an overall reduction in chemotherapy, the belief that Oncotype DX may have a potential role in neoadjuvant treatment planning and the company's plans regarding additional studies in this regard, the belief that certain study results provide a rationale for evaluating currently available and investigational agents that target certain pathways, 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.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX and Recurrence Score are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

(i) Chang JC, Makris A, Gutierrez MC, et al. Gene expression patterns in formalin-fixed, paraffin-embedded core biopsies predict docetaxel chemosensitivity in breast cancer patients. *Breast Cancer Res Treat.* 2008;108(2):233-240.

(ii) Gianni L, Zambetti M, Clark K, et al. Gene expression profiles in paraffin-embedded core biopsy tissue predict response to chemotherapy in women with locally advanced breast cancer. *J Clin Oncol.* 2005;23(29):7265-7277. Epub 2005 Sep 6.

(iii) Akashi-Tanaka S, Shimizu C, Masashi A, et al. 21-gene expression profile assay on core needle biopsies predicts responses to neoadjuvant endocrine therapy in breast cancer patients. *The Breast* 2009;18(3):171-174.

Video-Link Available: [http://www2.marketwire.com/mw/frame\\_mw?attachid=1137083](http://www2.marketwire.com/mw/frame_mw?attachid=1137083)

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