Genomic Health Study Shows Breast Cancers in Men Display Very Similar Gene Signatures to Those in Women

-- Largest Genomic Study Comparing Gene Expression in Female and Male Patients Presented at ASCO Annual Meeting --

ORLANDO, Fla., May 29, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from a study which summarized the gene signatures identified by the Oncotype DX(R) breast cancer test in a large number of male patients for whom the test was used to guide treatment with chemotherapy. The results, which will be presented in a poster presentation on Monday, June 1 (1:00 - 5:00 p.m. ET) at the American Society of Clinical Oncology (ASCO) annual meeting in Orlando, demonstrated that breast cancer in men displays similar gene signatures to female breast cancer.

"Breast cancer is not just a woman's disease, yet treatment for men is typically extrapolated from our experience in the female population since it is rare and there is little known about the biology of male breast cancer," said George Sledge, M.D., Ballve-Lantero Professor of Oncology at Indiana University in Indianapolis, and lead investigator of the study. "This is the largest genomic study to compare gene expression in female and male patients, and results support the clinical utility of Oncotype DX in providing quantitative information to help guide treatment decisions for men with breast cancer."

The study, "Molecular characterization of male breast cancer by standardized quantitative RT-PCR analysis: First large genomic study of 347 male breast cancers compared to 82,434 female breast cancers" (Abstract #549), analyzed quantitative gene expression by gender status in estrogen receptor (ER) positive tumor specimens. As with female breast cancer, a wide inter-patients variation was observed in gene expression in male breast cancer. The proportion of tumors with low risk of recurrence based on the Recurrence Score(R) was 53.6 percent in males versus 53.4 percent in females, intermediate risk of recurrence was 35.2 percent in males versus 36.3 percent in females, and high risk of recurrence was 11.2 percent in males versus 10.3 percent in females.

Despite the similarities between the two patient groups, there were also some differences. For example, male breast cancer patients had higher mean expression of the hormone receptor genes, likely due to the different hormonal context of men and women. In addition, male breast cancer patients were older, on average, and were less likely than women to have the lobular form of breast cancer.

"I was quite surprised when my doctor told me I had breast cancer and was not looking forward to the multiple rounds of chemotherapy that he originally recommended," said Mike Nelsen, a breast cancer patient from Baltimore. "After my Oncotype DX test results came back and I discussed them with my oncologist, I felt confident that I could avoid chemotherapy and its side effects without increasing the risk of my cancer returning."

Multiple Studies Highlight Application of Personalized Medicine in Oncology Setting

Additionally, Genomic Health, in partnership with investigators from several academic institutions, will present a separate study at ASCO evaluating the genotypic features of triple-negative breast cancer compared with hormone receptor-positive disease, as well as the genotypic features associated with recurrence. The study, "Genotypic characterization of phenotypically defined triple-negative breast cancer" (Abstract #500), demonstrated that there were significant differences in gene expression between the triple negative and hormone receptor positive groups, including genes for which targeted agents are currently being evaluated in the clinical environment. Full results will be discussed in an oral presentation on Sunday, May 31 (4:30 p.m. ET).

These presentations are in addition to Genomic Health's previously announced results regarding its Oncotype DX colon cancer test, from the landmark QUASAR validation study, demonstrating that the test can independently predict individual recurrence risk in stage II colon cancer patients following surgery. The study, "A quantitative multi-gene RT-PCR assay for prediction of recurrence in stage II colon cancer: Selection of the genes in 4 large studies and results of the independent, prospectively-designed QUASAR validation study" (Abstract #4000), which was highlighted on May 14 during ASCO's advance presscast, will be presented Saturday, May 30 (3:00 p.m. ET). Genomic Health plans to make its colon cancer test available to physicians and patients in early 2010.

"With these two breast cancer studies and the QUASAR colon cancer validation results, we continue to advance our
understanding of the role of genomics in cancer," said Steve Shak, M.D., chief medical officer of Genomic Health. "As a leader in personalized medicine, we are committed to further increasing the clinical utility of our tests through additional studies, while expanding research and development efforts for other tumor types in an effort to individualize treatment for all cancer patients."

About Oncotype DX(R)

The widely adopted Oncotype DX breast cancer assay is the first and only multi-gene 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 assay has been extensively evaluated in thirteen clinical studies involving more than 4,000 breast cancer patients, 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. To date, more than 7,500 physicians have ordered more than 100,000 tests, and both Medicare and private health plans covering more than 90 percent of U.S. insured lives provided reimbursement for Oncotype DX 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 [http://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(R) breast cancer test, which has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage breast cancer. The company was founded in 2000 and is located in Redwood City, California. For more information, please visit [http://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 applicability of clinical study results to actual outcomes, the company's plans to commercialize a test for colon cancer and the proposed timing of such commercialization, and the company's expectation that it will increase the clinical utility of its tests and expand its research and development efforts. 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 March 31, 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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