Genomic Health Announces Results from Biomarker Discovery Program Utilizing Next-Generation Sequencing to Compare Normal and Tumor Breast Tissue

Results Presented at the 12th Annual Advances in Genome Biology and Technology Meeting

REDWOOD CITY, Calif., Feb. 3, 2011 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced that its scientists successfully surveyed expression of the whole human transcriptome using next-generation DNA sequencing technology developed by Illumina, Inc., to test hypotheses for biomarker discovery in archived tumor and normal breast tissue samples. The study identified hundreds of coding and non-coding transcripts that are differentially expressed in tumor versus normal, non-cancerous breast tissue, including a subset of genes statistically associated with the recurrence of breast cancer. Additionally, novel candidate biomarkers from outside of the known protein-coding regions of the genome were discovered to be associated with recurrence of breast cancer. The findings were presented today at the 12th Annual Advances in Genome Biology and Technology (AGBT) meeting in Marco Island, Fla.

"These results demonstrate the use of next-generation sequencing of formalin-fixed tissue to accelerate testing of hypotheses for biomarker discovery," said Joffre Baker, Chief Scientific Officer at Genomic Health. "Our long-term goal for this and future studies is to validate the findings with large, well-designed clinical trials in an effort to connect either gene mutations or expression profiles to clinical outcomes and provide additional personalized information to physicians and patients beyond that already available through the use of Onco*type* DX®."

The study was designed to compare gene expression profiles between 12 normal and 12 tumor formalin-fixed (FFPE) breast specimens — all of which were 10-13 years old. Each sample, on average, yielded 19 million base pairs of DNA with approximately 85 percent mapping to unique sites in the human genome. Further analysis showed that 3,584 coding genes were differentially expressed between tumor and normal specimens. The association of each of these with the risk of breast cancer recurrence was sought by consulting published gene expression results from approximately 3,000 patients with breast cancer tumors for which there was a record of clinical outcome. This analysis showed that sets of transcripts over-expressed in tumors compared with normal tissues produced only a modest enrichment for prognostic significance, but further evaluation of these transcripts by gene set analysis produced a set that is highly enriched for prognostic genes.

In addition, an algorithm was developed to detect and quantify transcripts from non-coding regions of the genome and through this process more than 1,000 differentially expressed non-coding sequences were identified. Reverse transcriptase-polymerase chain reaction (RT-PCR) assays were designed for a number of the non-coding transcripts and were used to screen a 136 patient cohort of breast cancer specimens. Several of these non-coding RNAs proved to be associated with breast cancer recurrence risk.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is a molecular diagnostics company focused on the global development and commercialization of genomic-based clinical laboratory services that analyze the underlying biology of cancer allowing physicians and patients to make individualized treatment decisions. Its lead product, the Onco*type* DX® Breast Cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage ER+ breast cancer. In addition to this widely adopted test, Genomic Health provides the Onco*type* DX Colon Cancer test, the first multigene expression test developed for the assessment of risk of recurrence in patients with stage II disease. As of September 30, 2010, more than 10,000 physicians in over 55 countries had ordered more than 175,000 Onco*type* DX tests. Genomic Health has a robust pipeline focused on developing tests to optimize the treatment of prostate and renal cell cancers, as well as additional stages of breast and colon cancers. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. 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 our ability to generate similar results in further studies, the clinical utility of preliminary biomarkers; our ability to develop whole transcriptome and/or genome expression analysis for routine clinical study; the belief that whole genome expression may accelerate clinical or biomarker discovery; our ability to develop, validate or commercialize advanced diagnostics based upon such genome expression data; the timing of such studies and results; and the company's ability to accelerate its research and development efforts to move whole genome expression technology into clinical studies. 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 uncertainties associated with the regulation of our tests; the applicability of clinical study results

to actual outcomes; the risks and potential delays associated with such studies; 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, 2010. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

SOURCE Genomic Health, Inc.