December 9, 2016

Genomic Health Announces Results from Multiple Oncotype DX® Studies, Reinforcing its Impact in Delivering Precision Medicine to Breast Cancer Patients Around the World

Presentations at 2016 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) Highlight Unique Value of Oncotype DX in Tailoring Treatment Across the Breast Cancer Patient Journey

REDWOOD CITY, Calif., Dec. 9, 2016 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results from multiple studies demonstrating the unparalleled value of the Oncotype DX® test in individualizing breast cancer treatment decisions for patients with various stages of the disease. Presentations included two overviews of prospective outcomes data and clinical evidence supporting use of the test in early-stage breast cancer patients with node-positive and node-negative disease. Data also included new results from the Surveillance, Epidemiology, and End Results (SEER) Registry program of the National Cancer Institute (NCI) analyzing outcomes and clinical utility of the Breast Recurrence Score™ (RS) in patients with high-grade tumors, and findings from a clinical evaluation of the Breast DCIS Score™ in patients with ductal carcinoma in situ (DCIS).

"The clinical evidence generated by independent researchers and Genomic Health is paramount, highlighting the accuracy of Oncotype DX in predicting clinical outcomes and its unique value in providing physicians with critical genomic intelligence to enhance breast cancer treatment decisions and patient benefit," said Steven Shak, M.D., chief scientific officer, Genomic Health. "These latest Oncotype DX presentations further our understanding of breast cancer biology across the continuum of the disease, as well as our ability to fulfill the promise of precision medicine for breast cancer patients by providing rigorously studied, standard-of-care genomic testing."

Extensive summary of unprecedented body of clinical evidence reconfirms unsurpassed clinical validity and utility of Oncotype DX in breast cancer

The original clinical validation studies of the Oncotype DX Breast Recurrence Score were prospectively designed using archived tissue from legacy trials that had long-term outcomes (NSABP B-14 and B-20, TransATAC, and SWOG 8814). With more than 700,000 patients tested to date, an overview of clinical outcomes evidence confirms the original clinical validation results. The recently presented prospective outcomes data from four large independent studies - the SEER Registry in the United States, Clalit Health Services in Israel, the international **T**rial **A**ssigning **I**ndividua**L**ized **O**ptions for Treatment (**Rx**), or TAILORx, and the West German Study Group "Plan B" trial - indicate that patients with node-negative and node-positive disease and low RS results (less than 18) can be effectively treated with hormonal therapy alone and spared the toxicity of chemotherapy.

"These data, drawn from outcomes of tens of thousands of patients from around the globe, show that the Recurrence Score has successfully transitioned genomic testing in breast cancer from academic research into an intervention with an impact on public health, sparing thousands of women around the world from unnecessary chemotherapy each year," said Harold J. Burstein, M.D., Ph.D., Dana-Farber Cancer Institute and Harvard Medical School. "They also extend the usefulness of genomics into populations such as women with node-positive breast cancers or high-grade tumors - situations where we have historically used chemotherapy, but where we may now rethink the need for that treatment."

SEER study of breast cancer-specific survival (BCSS) in patients with high-grade tumors treated based on Oncotype DX results shows many patients have excellent outcomes without chemotherapy

An analysis of clinical outcomes in 9,201 patients with node-negative and node-positive disease and poorly differentiated tumors demonstrated a wide distribution of the Oncotype DX Breast Recurrence Score results and showed the test was a strong predictor of BCSS ($p < 0.001$). Of these patients, those with RS less than 18 had excellent five-year BCSS (> 99 percent) regardless of tumor size and nodal status. Although patients with poorly differentiated tumors are well known to have worse prognosis on average, the test identified a sizable proportion of patients who can expect favorable five-year BCSS.

Comprehensive review of clinical evidence confirms Oncotype DX accurately predicts clinical outcomes in node-positive breast cancer patients, supporting use of the test by physicians and patients, inclusion in guidelines and recognition by payors

A systematic review was conducted across seven studies including more than 8,000 patients with node-positive disease. These studies consistently identified patients with a low number of positive nodes and low RS results who had good clinical outcomes without chemotherapy. The use of Oncotype DX in node-positive breast cancer significantly decreased the

frequency of adjuvant chemotherapy recommendations and was found to be a cost-effective and/or cost-saving approach worldwide.

Multi-center study demonstrates Oncotype DX predicts neoadjuvant chemotherapy benefit
A prospective multi-center study of 64 patients with early-stage invasive breast cancer not suitable for breast-conserving surgery showed that patients with a RS less than 11 had a high clinical response rate with neoadjuvant hormone therapy, and 75 percent were able to get breast-conserving surgery. Patients with a RS between 11 and 25 who received neoadjuvant hormonal therapy also had a high rate of successful breast-conserving surgery. Conversely, patients with a RS over 25 benefited from neoadjuvant chemotherapy and had excellent results. These results reinforce the unmatched utility of Oncotype DX in predicting chemotherapy benefit for early-stage invasive breast cancer.

Independently conducted comparison of clinical factors and Oncotype DX shows Breast DCIS Score is substantially discordant from clinical prognostic tools
A study in 91 patients with DCIS compared the use of commonly available clinical prognostic tools and physician estimates with the Oncotype DX Breast DCIS Score to determine ipsilateral breast event risks post-lumpectomy. Results showed that ipsilateral breast event risk estimates varied significantly (more than 30 percent) among the commonly available clinical predictive tools and individual physician estimates, and none reliably replicated the Breast DCIS Score. These results underscore the unique value of the Breast DCIS Score.

Additional Oncotype DX presentations at the 2016 SABCS included the following:

- A prospective multi-center decision impact study of 603 patients from France demonstrated that the use of the Oncotype DX test changed treatment decisions in 70 percent of patients and reduced the use of chemotherapy, resulting in an estimated cost savings of 570 euros per patient. These results, based on real-world clinical practice in France, indicate that molecular testing provides additional clinically meaningful information for a significant proportion of patients and support its use and public reimbursement.

- A gene discovery study conducted in collaboration with SWOG, an NCI cooperative group, identified new genes and pathways that may serve important roles in determining the prognosis of late breast cancer-specific events (BCSE) in patients taking tamoxifen alone. The study showed that the biology of late recurrence is very different from the biology of early recurrence - an important finding for liquid biopsy tests, which may be better suited to predict late recurrence based on evolution of the tumor.

- Two trial designs were presented, including one for an ongoing study in 150 patients with a diagnosis of ER-positive, HER2-negative primary metastatic breast cancer. The study is evaluating the association of Oncotype DX Breast Recurrence Score results with time to progression and overall survival.

About Oncotype DX®

The Oncotype DX® portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. The company's flagship product, the Oncotype DX breast cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. With more than 700,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeDX.com or www.MyBreastCancerTreatment.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimize cancer care by addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ™ Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX gene expression tests that have been used to guide treatment decisions for more than 700,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select assay. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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, 2016. 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, Recurrence Score, DCIS Score, Oncotype SEQ, and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

GHDX-B

Logo - http://photos.prnewswire.com/prnh/20130425/SF01493LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/genomic-health-announces-results-from-multiple-oncotype-dx-studies-reinforcing-its-impact-in-delivering-precision-medicine-to-breast-cancer-patients-around-the-world-300375808.html

SOURCE Genomic Health, Inc.