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New "Big Data" Brings Total Number of Breast Cancer Patients Studied to 50,000, Demonstrating Oncotype DX® Accurately Predicts Clinical Outcomes

Presentations at SABCS from SEER Registry, TAILORx and Clalit Studies Establish Oncotype DX as the Only Multi-gene Breast Cancer Test with Industry-leading Level of Prospective Outcomes Evidence Next-generation Sequencing Gene Discovery Reveals Opportunity for Liquid Biopsy to Help Guide Late-recurrence Treatment Decisions

REDWOOD CITY, Calif., Dec. 15, 2015 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from multiple Oncotype DX® breast cancer test studies at the 38th CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) reconfirming that Oncotype DX accurately predicts clinical outcomes - including risk of recurrence and breast cancer survival - in early-stage patients with invasive breast cancer. Data include results from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute (NCI); complete results from a multi-center study from Clalit Health Services, the largest Health Maintenance Organization in Israel; and additional analysis from the **T**rial **A**ssigning **I**ndividua**L**ized **O**ptions for Treatment (**Rx**), or TAILORx, led by the ECOG-ACRIN Cancer Research Group.

"We now have an unprecedented amount of data from four large, independently run, international studies demonstrating that Oncotype DX transforms both treatment decisions and prospective patient outcomes," said Steven Shak, M.D., chief scientific officer, Genomic Health. "These results provide unequivocal evidence supporting the expert-derived clinical practice guidelines on the clinical utility of Oncotype DX in node-negative and node-positive disease, and demonstrate that patients and their physicians can make much better informed decisions based on the Recurrence Score result."

Evidence in Over 44,500 Patients Shows that Oncotype DX Accurately Predicts Patient Outcomes; Patients with Recurrence Score® Less than 18 Have Excellent Breast Cancer Survival at Five Years

SEER is the premier source of cancer statistics in the United States, collecting incidence and cancer survival data for 30 percent of all U.S. cancer patients.

A large population-based observational study based on the SEER registry of more than 40,000 node-negative and 4,500 node-positive patients showed Breast Cancer Specific Mortality (BCSM) at five years was less than half a percent in node-negative disease and one percent in node-positive disease (up to three positive nodes) when the Recurrence Score results were less than 18.

Another important finding was that mortality increased with increasing Recurrence Score results ($p < 0.001$), underscoring the accuracy of Oncotype DX in predicting patient outcomes. BCSM increased slightly among patients with intermediate Recurrence Score results of 18-30, and more than tenfold in patients with high Recurrence Score results equal to or greater than 31. Analyses that included patient age, tumor size and grade showed that the Recurrence Score provided information beyond those standard measures ($p < 0.001$).

The SEER program and Genomic Health are collaborating to gain important clinical insights from patients who have been treated and tracked through the comprehensive NCI-affiliated registry to help improve the diagnosis and treatment of breast cancer.

SEER Results Reveal Disparities in Oncotype DX Testing and Outcomes Dependent on Patient Age and Geographic Location

Based on the most recent analysis of patient information from the year 2012, on average, 41 percent of patients with node-negative, hormone-positive, HER2-negative breast cancer had the Oncotype DX test performed. The use of Oncotype DX and chemotherapy varied greatly based on patient age or geographical location. Patients 70 years of age or older with node-negative breast cancer - a subgroup that showed significantly worse breast cancer survival and lower chemotherapy use across all of SEER registry - were more than three times less likely to be tested on average than patients younger than age 70. In addition, a significant variability in testing was observed among the 12 states included in the SEER database, with much lower rates of Oncotype DX testing performed in 2012 in California (32 percent) and Washington (33 percent).

"Electronically supplementing the SEER registry with the Genomic Health breast cancer test results providesÂ helpful information onÂ the use of this testÂ to enhance ourÂ understanding of breastÂ cancer diagnosis, treatment and outcomes," said Lynne Penberthy, M.D., M.P.H., associate director of the Surveillance Research Program, NCI'sÂ Division of Cancer Control and Population Sciences.

Oncotype DX Recurrence Score results were provided to SEER as mandated by registry operations. There are plans to broaden this collaboration on data sharing and to continue to supplement the SEER registry with Oncotype DX testing information on an annual basis.Â SEER and Genomic Health intend to publish this study's findings and to further analyze results regarding the use of Oncotype DX within the NCCN-recommended patient criteria and in broader patient groups.Â Genomic Health's reporting of the SEER registry data on Oncotype DX is self-funded, and there is no financial relationship between the NCI and Genomic Health.

Three Additional Large International Studies Reinforce Ability of Oncotype DX to Predict Clinical Outcomes, Reconfirming Worldwide Value of the Test in Guiding Treatment

A study from Clalit Health Services analyzed medical records of 2,028 patients with node-negative and node-positive disease with micrometastases across nine medical centers. Oncotype DX was used in clinical practice in all of the patients to assign treatment with or without chemotherapy. Results showed that the 996 women with low Recurrence Score results less than 18 who were largely treated with hormonal therapy alone (98 percent) had excellent outcomes with less than one percent chance of distant recurrence or breast cancer specific mortality at five years. In addition, the 812 patients with intermediate Recurrence Score results of 18 to 30, who were treated 28 percent of the time with chemotherapy, had only slightly higher rates of distant recurrence (3.2 percent) and breast cancer specific mortality (1.1 percent) at five years.

Separately, results of the initial analysis of TAILORx, which were recently published in *The New England Journal of Medicine*, were presented at SABCS along with an additional analysis of the correlation of the Oncotype DX single gene scores with clinicopathological measures. Key findings, previously reported, demonstrated that trial participants with Recurrence Score results of less than 11 who received hormonal therapy alone had less than a one percent chance of distant recurrence at five years. Similar findings regarding prospective outcomes for Oncotype DX-tested patients were recently reported at the European Cancer Congress by the Women's Healthcare Study Group. This separate study across more than 90 centers in Germany analyzed outcomes in more than 2,500 patients from one of Europe's largest contemporary adjuvant breast cancer trials.

"Consistent with results from the prospective-retrospective NSABP and SWOG clinical validation studies of Oncotype DX, the new multiple prospective outcomes studies provide additional strong evidence of the test's ability to accurately predict prospective outcomes regardless of age, tumor size or grade," said Norman Wolmark, M.D., chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP). "This is a significant milestone in genomics and reconfirms, for the first time, the undeniable clinical value of Oncotype DX in selecting patients for chemotherapy treatment."

Next-generation Sequencing (NGS) Study Showcases Genomic Health's Scientific Leadership in Generating and Analyzing "Big Data"

A gene discovery study conducted by the NCI cooperative group, SWOG, identified a number of new genes and pathways that may be important in early breast cancer recurrence or response to chemotherapy. The study also showed that the biology of late recurrence was very different from the biology for early recurrence. This is a particularly important finding because it provides an opportunity for a new technology such as liquid biopsy - which may be better suited to predict late recurrence based on evolution of the tumor - to help guide duration of hormonal therapy and to track cancer progression and drug resistance.

Also presented at the 2015 SABCS was a second decision impact study of Oncotype DX in DCIS (ductal carcinoma in situ) across 13 centers in the United States. Results demonstrated that the test significantly changes treatment decisions, reinforcing previously published results and providing further confidence to physicians and their patients as they include the test in treatment decision-making.

About Oncotype DX®

The Oncotype DX®Â 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 over half a million 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 breast cancer tests, visit:Â www.OncotypeDX.com Â or www.mybreastcancertreatment.org.

AboutÂ Genomic HealthÂ

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early-stage cancer, one of the greatest issues in healthcare today. The company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of massive amounts of genomic dataÂ into clinically-actionable results for treatment planning throughout the cancer patient's journey, from diagnosis to treatment selection and monitoring.Â The company is based inÂ Redwood City,Â California,Â with international headquarters inÂ Geneva,Â Switzerland. For more information, please visit,Â www.GenomicHealth.comÂ and follow the company on Twitter: @GenomicHealth, Facebook, YouTubeÂ and LinkedIn.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of the test to physicians, patients and payors. 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 ability of test results to change treatment decisions or outcomes; the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; unanticipated costs, delays or other challenges in research and development efforts including for new products; and the other risks set forth in the company's filings with theÂ Securities and Exchange Commission, including the risks set forth in the company's quarterly report on Form 10-Q for the quarter endedÂ September 30, 2015. These forward-looking statements speak only as of the date hereof.Â Genomic HealthÂ disclaims any obligation to update these forward-looking statements.

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