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Genomic Health Announces Five-year Outcomes from International 'PlanB' Study Demonstrating the Clinical Utility of Oncotype DX® in Node-positive and High-risk Node-negative Breast Cancer

One of the Largest Contemporary Adjuvant Breast Cancer Trials in Europe Shows that Patients with Low Oncotype DX® Scores Can Be Spared Chemotherapy Even When Traditional Factors Indicate Higher-Risk Disease

AMSTERDAM, March 11, 2016 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced new five-year clinical outcomes results from a large PlanB study, which was highlighted as an oral presentation at the 10th European Breast Cancer Conference (EBCC-10)[1] in Amsterdam, Netherlands. The study, conducted by the West German Study Group (WSG), showed that 94 percent of early-stage breast cancer patients with Oncotype DX® Recurrence Score® results of 11 or less, who were treated with hormonal therapy alone, were disease-free five years after diagnosis.

These new PlanB study results with five-year outcomes provide information beyond the three-year outcomes published recently in the *Journal of Clinical Oncology*. The results add to the unprecedented amount of clinical outcomes data on Oncotype DX and are consistent with conclusions of the **T**rial **A**ssigning **I**ndividua**L**ized **O**ptions for Treatment (**Rx**), or TAILORx, recently published in *The New England Journal of Medicine*, and results from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute (NCI), recently presented at the San Antonio Breast Cancer Symposium.

"Our study shows the unique value of adding biologic information provided by the Oncotype DX test in order to identify low-risk breast cancer patients - among patients with 0-3 involved lymph nodes - who can safely be spared the toxicity and side effects of chemotherapy without compromising outcomes," said Prof. Nadia Harbeck, WSG scientific director and head of the breast center at University of Munich (LMU). "This is especially important for patients who would be considered as intermediate to high risk of recurrence based on traditional clinical parameters. These results confirm previous retrospective studies with Oncotype DX, as well as the prospective TAILORx trial, which already provided results for the node-negative population."

The study, conducted at 93 centers across Germany enrolled more than 3,100 patients with estrogen-receptor positive, HER2-negative, early-stage breast cancer, including those with node-positive disease (up to three nodes) who were considered candidates for chemotherapy by traditional parameters. The Oncotype DX test was used on all patients to identify those who could be spared adjuvant chemotherapy despite being considered as having high clinical risk disease by traditional parameters. Participants with Recurrence Score results of 12 or higher were randomized to different chemotherapy regimens, and patients with Recurrence Score results of 11 or less were treated with hormonal therapy alone.

In women with Recurrence Score results of 11 or less who were treated with hormonal therapy alone, five-year disease free survival (DFS) was estimated as 94 percent. Patients with Recurrence Score results of 12 to 25 who were treated with adjuvant chemotherapy also had high DFS rates of 94 percent, while in patients with Recurrence Score results above 25 who had also received chemotherapy, DFS rates were 84 percent.

"The compelling suite of new global prospective outcomes data generated in the last six months supports our prior validation work and all of the guidelines worldwide that include Oncotype DX to select patients for chemotherapy treatment, while providing physicians and patients with the highest level of evidence supporting the Recurrence Score as standard of care," said Steven Shak, M.D., chief scientific officer, Genomic Health.

Most recently, the German Association of Gynecological Oncology's (AGO's) treatment guidelines distinguished Oncotype DX as the first and only multi-gene breast cancer test with the highest 1A level of evidence, following publication of multiple large prospective outcomes studies. The AGO guidelines also reconfirmed Oncotype DX as the only multi-gene expression test validated to provide predictive information on the likelihood of chemotherapy benefit for women with early-stage, hormone-receptor positive, HER2-negative invasive breast cancer.

"Value in health care depends on results and outcomes, which is vital to the patient. Results from this study clearly show the

value benefit of a personalized approach to breast cancer treatment," said Denis Horgan, executive director of the European Alliance for Personalized Medicine. "We hope to see more healthcare systems across Europe provide access to molecular diagnostics that are supported by a high level of scientific evidence and proven clinical utility."

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 600,000 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 breast cancer 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 address both the overtreatment and optimal treatment of cancer, 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 600,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests. 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, 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; the results of clinical studies; 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 annual report on Form 10-K for the year ended December 31, 2015. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

[1]Abstract no: 8 LBA. "Prospective WSG Phase III PlanB trial: Clinical outcome at 5-year follow up and impact of 21 Gene Recurrence Score result, central/local-pathological review of grade, ER, PR and Ki67 in HR+/HER2- high risk node-negative and -positive breast cancer", Friday, Plenary session: oral and late breaking abstracts, 09.45-11.15 hrs, Elicium.

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