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Journal of Clinical Oncology Publishes Prospective Outcomes Results from Large International Trial Using Oncotype DX®

New Publication of Results from 'PlanB' Study Reinforces Unique Value of Oncotype DX, the Only Multi-gene Breast Cancer Test with Prospective Outcomes Evidence in More Than 50,000 Patients Five-year Results Accepted for Oral Presentation at European Breast Cancer Conference, Included in Official Congress Press Program

REDWOOD CITY, Calif., March 1, 2016 /PRNewswire/ -- [Genomic Health](#), Inc. (Nasdaq: GHDX) today announced that the [Journal of Clinical Oncology](#) published clinical outcomes results from PlanB, one of Europe's largest adjuvant studies that utilized the Oncotype DX® breast cancer test to assign treatment. Led by the West German Study Group (WSG) in Germany, results from the PlanB study showed that women with Oncotype DX Recurrence Score® results of 11 or less had excellent outcomes with 98 percent disease-free survival rates at three years, despite having high-risk disease by traditional parameters. This finding is consistent with conclusions of the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, recently published in [The New England Journal of Medicine](#), adding to the unprecedented body of evidence demonstrating that Oncotype DX accurately predicts outcomes, including breast cancer recurrence and survival, in data collected from more than 50,000 patients.

"The compelling suite of new global prospective outcomes data generated in the last six months proves that tens of thousands of patients worldwide can forgo chemotherapy and its harmful side effects based on a low Recurrence Score," said Steven Shak, M.D., chief scientific officer, Genomic Health. "Not only do these collective results support our prior validation work and all of the guidelines worldwide that include Oncotype DX to select patients for chemotherapy treatment, they also provide physicians with the highest level of evidence to support using the test as standard of care."

This large study, conducted in 93 centers across Germany, enrolled more than 3,100 patients with high-risk, estrogen-receptor positive, HER2-negative early-stage breast cancer, including those with node-positive disease who were considered candidates for chemotherapy by traditional parameters. Oncotype DX Recurrence Score results were used to identify patients who would be spared adjuvant chemotherapy despite being considered as having high clinical risk 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.

The study showed that women with Recurrence Score results of 11 or less had excellent outcomes at three years despite having high-risk disease by traditional parameters, such as nodal status. The results indicate that chemotherapy can safely be spared in patients with high clinical risk of recurrence - including node-positive disease - if the Recurrence Score result is 11 or less.

"Our study results show that a low Recurrence Score result identifies patients who can be safely spared chemotherapy without compromising outcomes. These results confirm previous retrospective studies as well as the prospective TAILORx trial," said Prof. Nadia Harbeck, WSG Scientific Director and Head of the breast cancer unit at University of Munich, Germany.

Findings from the PlanB study also suggest there may be overtreatment in a substantial subset of patients who have Recurrence Score results between 12 and 25, as patients in this range also had excellent outcomes with disease-free survival of 98 percent at three years. These findings add to a recent study from Clalit Health Services, the largest Health Maintenance Organization in Israel, that showed that women with Recurrence Score results of less than 18 who were largely treated with hormonal therapy alone had excellent outcomes with less than a one percent chance of distant recurrence or breast cancer-specific mortality at five years.

"Patients should only get chemotherapy with all its side effects if they are going to benefit substantially. Gene expression tests often play an important role in making this decision," said Renate Haidinger, president of the German Breast Cancer

Association, the leading national patient advocacy organization in Germany. "Based on the latest study results, we hope that patients can get broad access to this test."

Five-year results from PlanB will be highlighted in the official [European Breast Cancer Conference](#) (EBCC-10) press program on Thursday, March 10, followed by the oral presentation on Friday, March 11, at a plenary session.

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 yearly report on Form 10-Q for the quarter ended Sept, 30, 2015. 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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