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Multiple Presentations at 15th St. Gallen International Breast Cancer Conference Demonstrate Significant Impact of Oncotype DX Breast Recurrence Score® in Reducing Burden and Cost of Chemotherapy

New Findings Reinforce Breast Recurrence Score™ as Only Genomic Test to Guide Chemotherapy Decisions in Node-negative and Node-positive Disease and Support Growing Adoption of Test

REDWOOD CITY, Calif., March 20, 2017 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from 15 Oncotype DX Breast Recurrence Score® studies conducted in 12 countries that provide real-world evidence of the test's ability to change treatment decisions in breast cancer patients. The new findings, presented at the [15th St. Gallen International Breast Cancer Conference](#) in Vienna, demonstrate the economic value of the test across multiple healthcare systems and reinforce the clinical validation, accuracy and precision of the Breast Recurrence Score™ in various early-stage breast cancer patient populations, including those with node-positive disease.

"Precision medicine is no longer just a promise - it is a reality for the more than 700,000 cancer patients tested to date for whom Oncotype DX has individualized care based on the biology of their tumor," said Steven Shak, M.D., chief scientific officer, Genomic Health. "The extensive scientific evidence on the clinical and health economic value of the Oncotype DX Breast Recurrence Score is unsurpassed as evidenced by its inclusion in all major global guidelines. We look forward to the publication of the updated St. Gallen International Expert Consensus Panel report, which has recognized Oncotype DX as the leading test to guide chemotherapy decisions since 2011."

In addition, the American Joint Committee on Cancer (AJCC) recently incorporated the Oncotype DX test in its updated published [Eighth Edition AJCC Cancer Staging Manual](#), identifying Oncotype DX as the only multi-gene test with Level I evidence to determine formal staging of breast cancer patients, based on prospective outcomes in more than 63,000 patients.

New data presented last week at the St. Gallen International Breast Cancer Conference include:

Three studies involving more than 8,000 node-positive breast cancer patients showed those with a low Oncotype DX Breast Recurrence Score (RS) had excellent outcomes at five years

- | An analysis of the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI) of 6,768 patients with lymph node-positive disease (including micrometastases) found that the five-year breast cancer-specific survival (BCSS) rate was excellent for those with a RS of less than 18, particularly among those with micrometastases and fewer positive lymph nodes. Five-year BCSS outcomes for those with a RS less than 18 ranged from 98.9 percent for those with micrometastases to 92.8 percent for those with four or more positive lymph nodes. The RS was strongly predictive of BCSS among patients with micrometastases or one to three positive lymph nodes (both $p < 0.001$). These findings in node-positive disease were recently updated and published in [Breast Cancer Research and Treatment](#), providing further detail on the five-year outcomes results previously published in [Nature Partner Journals Breast Cancer](#).
- | A study from Clalit Health Services in Israel followed over 700 patients for a median of 5.9 years. The results showed that patients with a RS less than 18 with micrometastases and one to three positive nodes had very good outcomes with the rates of distant recurrence of three percent at five years. The majority of these patients (93 percent) were treated with hormonal therapy alone.
- | A prospective analysis of more than 770 patients from the Plan B trial conducted by the West German Study Group in Germany showed that patients with a RS of 11 or less had an excellent five-year disease free survival rate of 94 percent when treated with hormone therapy alone without chemotherapy.

Collectively, these results are consistent with two separate comprehensive reviews conducted by independent physician groups who have used the Oncotype DX Breast Recurrence Score in clinical practice when treating node-positive patients. A comprehensive summary led by Terry Mamounas M.D., M.P.H., FACS, UF Health Cancer Center in Orlando, Fla., included seven international studies involving more than 9,000 patients with node-positive disease. Additionally, Dr. Jeremy P. Braybrook, Bristol Cancer Institute, University Hospitals Bristol NHS Foundation Trust, Bristol, U.K., reported a pooled analysis of international studies in 385 patients with one to three positive lymph nodes showed that testing with the Breast

Recurrence Score significantly impacted treatment decisions (43 percent), resulting in a net reduction in chemotherapy use in real-world clinical practice.

Multiple studies from Germany and France reconfirm clinical and health economic value of Oncotype DX Breast Recurrence Score, supporting broader adoption of the test in Western Europe

- 1 A detailed budget impact assessment in Germany comparing the Breast Recurrence Score to other prognostic-only genomic tests identified the Breast Recurrence Score as the test associated with the highest reduction in chemotherapy use because it appropriately classifies more patients as low risk than other assays, resulting in net budget savings of more than EUR 4,001 per patient.
- 1 Two studies from France, including a treatment decision analysis based on real-world clinical experience in 827 patients, demonstrated that the test significantly reduced the use of chemotherapy by 35 percent.

These results are consistent with findings from a review of eight other international studies that included more than 2,500 patients and demonstrated that Breast Recurrence Score testing led to an approximate 40 percent reduction in chemotherapy use in node-negative breast cancer.

"These new findings, based on results from thousands of patients in the U.S. and Europe, provide more evidence of the value of Oncotype DX in deciding whether chemotherapy is needed or not for women with both node-negative and node-positive breast cancer," said professor Ian Smith, consultant medical oncologist, professor of cancer medicine, Royal Marsden Hospital, London. "This genomic test has already spared thousands of patients from unnecessary chemotherapy and reduced healthcare costs worldwide."

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 Recurrence Score, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Breast DCIS Score™ 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™. 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. 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: our business model; the applicability of clinical study results to actual outcomes; the impact of results from clinical studies on market adoption and utilization of Oncotype DX® tests, our ability to develop and commercialize new tests and expand into new markets domestically and internationally; unanticipated costs or delays in research and development efforts; 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-K for the year ended December 31, 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, Genomic Health, Oncotype, Oncotype DX, Breast Recurrence Score, Recurrence Score, DCIS Score, Oncotype SEQ, Liquid Select, Genomic Prostate Score, Oncotype AR-V7 Nucleus Detect 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.



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