



Multiple Oncotype DX Study Presentations at the 2018 San Antonio Breast Cancer Symposium Reinforce Real-world Value of the Oncotype DX Breast Recurrence Score® Test in Patients Regardless of Age or Race

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REDWOOD CITY, Calif., Dec. 10, 2018 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results from multiple Oncotype DX Breast Recurrence Score® (RS) presentations at the 2018 San Antonio Breast Cancer Symposium® (SABCS), reinforcing the value of the Oncotype DX® test in optimizing treatment and outcomes in patients with both node-negative and node-positive early-stage breast cancer.

Among the data presented at SABCS are two presentations from investigators involved in the landmark TAILORx (Trial Assigning Individualized Options for Treatment (Rx)) trial, which provided independent analysis using the Oncotype DX test to gain further information about chemotherapy benefit across ethnic groups and chemotherapy effect on quality of life. Other presentations included the first report of long-term outcomes from the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI) on early-stage patients with node-positive disease not treated with chemotherapy and the first study specifically focused on the Oncotype DX test in women less than 40 years of age.

"With the practice-changing results of TAILORx and new real-world evidence in more than 80,000 patients, the Oncotype DX test is being increasingly used in the United States and around the world to contribute to smarter cancer care and improved outcomes for breast cancer patients," said [Steven Shak, M.D., chief scientific officer and chief medical officer, Genomic Health](#).

Independent Analyses Reinforce TAILORx Conclusions

As follow-up to the TAILORx results that were published by the ECOG-ACRIN Cancer Research Group in the *New England Journal of Medicine* in June 2018, Kathy S. Albain, M.D., FACP, professor of medicine, Loyola University Chicago Stritch School of Medicine, evaluated outcomes among patients of different races and/or ethnic backgrounds. These findings reported at SABCS reinforce the original TAILORx results, showing that chemotherapy in early-stage breast cancer can be safely avoided if the Recurrence Score result is less than 26 in women of all races/ethnicities, including Black, Hispanic and Asian women.

Results of a separate TAILORx sub-study, presented at SABCS by Lynne I. Wagner, Ph.D., professor, Social Sciences and Health Policy at Wake Forest School of Medicine, provide additional evidence regarding the negative impact of chemotherapy on patient quality of life. These results underscore the value of the Oncotype DX Breast Recurrence Score® in avoiding unnecessary chemotherapy in the majority of patients with node-negative breast cancer.

Additionally, real-world evidence from a more than 80,000 patient study based on an analysis of data from the SEER registry program of the NCI reinforced findings from multiple clinical trials, including TAILORx, and confirmed that the Oncotype DX Breast Recurrence Score result is predictive of chemotherapy benefit in patients with node-negative disease ($p=0.009$), with no chemotherapy benefit with RS results less than 26. In patients with node-negative disease and RS results less than 26 not treated with chemotherapy, the Breast Cancer Specific Survival (BCSS) was greater than 96 percent at nine years. In patients with node-positive disease not treated with chemotherapy and RS results less than 18, BCSS was greater than 97 percent at nine years.

"The SEER nine-year real-world evidence supports the new TAILORx-defined paradigm for Recurrence Score-guided chemotherapy treatment using the cutoff of 26," said Gabriel N. Hortobagyi, M.D., FACP, program director, Department of Breast Medical Oncology, Division of Susan G. Komen Interdisciplinary Breast Fellowship Program, The University of Texas MD Anderson Cancer Center. "Importantly, these long-term SEER results also support the option of hormone therapy alone for patients with one to three positive nodes and an Oncotype DX Recurrence Score less than 18."

Finally, investigators at Dana-Farber led a multi-center study to prospectively analyze Oncotype DX test results in 500 young women with node-positive and node-negative breast cancer. The findings showed very good outcomes for those with a RS of 0 to 25 who were not treated with chemotherapy. These results provide further evidence of the unique value of the Oncotype DX test to guide chemotherapy treatment decision-making in early-stage breast cancer in patients age 40 or younger.

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 950,000 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, including 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 950,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ test. 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](https://twitter.com/GenomicHealth), [Facebook](https://www.facebook.com/GenomicHealth), [YouTube](https://www.youtube.com/GenomicHealth) and [LinkedIn](https://www.linkedin.com/company/genomichealth).

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 Oncotype DX Breast Recurrence Score 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 results of clinical studies, including the TAILORx study; the applicability of clinical study results to actual outcomes; the ability of the test results to change treatment decisions and improve patient outcomes; the risks and uncertainties associated with the regulation of the company's tests; 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 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 annual report filed on Form 10-Q for the year ended September 30, 2018. 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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Investors: Emily Faucette, Genomic Health, 650-569-2824, investors@genomichealth.com; Media: Victoria Steiner, Genomic Health, 415-370-5804, media@genomichealth.com