



## New TAILORx Data, Published Today in JAMA Oncology, Add to Strong Evidence Base Reinforcing Unique Ability of Oncotype DX Breast Recurrence Score® Test to Guide Chemotherapy Treatment

September 30, 2019

**Clinical Outcomes in Patients with High Recurrence Score® Results Presented Today in Oral Session at ESMO 2019 Congress**

**With Fourth Peer-Reviewed Publication, TAILORx Continues to Elevate Oncotype DX® Test to a New Global Standard**

REDWOOD CITY, Calif., Sept. 30, 2019 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results from a new analysis of the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, which reinforce the unique value of the Oncotype DX Breast Recurrence Score® test to guide the use of adjuvant chemotherapy for women with hormone receptor-positive (HR+), HER2-negative, early-stage breast cancer and identify those patients who derive a significant benefit from treatment. The findings, published today in *JAMA Oncology*<sup>1</sup> and presented at the ESMO 2019 Congress<sup>2</sup>, are consistent with results from the B20 trial<sup>3</sup> and show that, in patients with high Recurrence Score results (26-100) treated with endocrine therapy plus chemotherapy, outcomes were better compared to what would be expected with endocrine therapy alone. The analysis also provides details on the outcomes of different chemotherapy regimens for the minority of patients who benefit from chemotherapy.

"We're pleased to see that the landmark TAILORx trial continues to receive global recognition, as evidenced by this fourth peer-reviewed publication," said Steven Shak, M.D., chief scientific officer, Genomic Health. "TAILORx established that the Oncotype DX test definitively identifies the vast majority of women with early-stage breast cancer who receive no benefit from chemotherapy and the important minority for whom chemotherapy can be life-saving. The additional insight from this new analysis is consistent with, and further supports, the conclusion that the Recurrence Score predicts which patients benefit from chemotherapy and which patients do not, giving them the standard of care they deserve."

The objective of this secondary analysis of TAILORx, the largest ever breast cancer treatment trial, sponsored by the National Cancer Institute (NCI) and led by the ECOG-ACRIN Cancer Research Group, was to evaluate clinical outcomes for patients with a high Recurrence Score result assigned to receive adjuvant chemotherapy plus endocrine therapy. In this group of 1,389 women, treated largely with standard of care taxane and/or anthracycline-containing adjuvant chemotherapy regimens, the estimated proportion free from distant recurrence at five years was about 93%, an outcome much better than expected with endocrine therapy alone in this population.

"Last year, TAILORx established the highest level of evidence and unprecedented precision supporting the use of the Oncotype DX Breast Recurrence Score test to guide adjuvant chemotherapy treatment for women with early-stage breast cancer," said lead author Joseph A. Sparano, M.D., associate director for clinical research at the Albert Einstein Cancer Center and Montefiore Health System in New York, and vice chair of the ECOG-ACRIN Cancer Research Group. "This new analysis provides the largest dataset on outcomes in patients with high Recurrence Score results, and confirms the importance of using the test to identify the patients who will receive a significant benefit from adding adjuvant chemotherapy."

The groundbreaking TAILORx results, presented during the Plenary Session at the 2018 ASCO Annual Meeting and simultaneously published in [The New England Journal of Medicine](#), have elevated the Oncotype DX test to a new standard of care with increasing, and more consistent, use of the test by physicians worldwide for all medically eligible patients. The study is also having an important impact on global reimbursement of the test, most recently in Germany and Italy. Following the German Institute for Quality and Efficiency in Health Care's (IQWiG's) positive [assessment](#) of the TAILORx results, the German Federal Joint Committee (G-BA) issued an exclusive nationwide [reimbursement decision](#) for the Oncotype DX test. In Italy, the Lombardy Regional Authority adopted a resolution to include the test in the Regional Health Service Fees List, thereby making it available as of September 1, 2019, to eligible patients living in the region.

Over the last several months, results of the TAILORx study have also influenced positive treatment guideline updates distinguishing the Oncotype DX Breast Recurrence Score test from prognostic-only tests based on clinical evidence and the critical importance of predicting chemotherapy benefit. The updates include:

- The recent update to [ASCO guidelines](#), which increased the proportion of women who can be effectively treated without chemotherapy based on the Recurrence Score results, highlighting the importance of testing all medically eligible early-stage breast cancer patients.
- The [National Comprehensive Cancer Network \(NCCN\)](#), which updated its guidelines in 2018 to categorize the Breast Recurrence Score test as the only "preferred" test for chemotherapy treatment decision-making for patients with node-negative, early-stage breast cancer. NCCN also classified the Breast Recurrence Score test as the only test that is predictive of chemotherapy benefit.
- The new [St. Gallen International Breast Cancer Guidelines](#), which recommend the Oncotype DX test to guide

chemotherapy treatment use for patients with hormone-receptor positive, HER-2 negative, early-stage breast cancer with and without lymph node involvement (up to three positive nodes).

- The updated [ESMO guidelines for early-stage breast cancer](#), which elevated the Oncotype DX test to highest 1A level of evidence and refer to TAILORx and PlanB results, which identify groups of patients – both in the node-negative and node-positive setting – for whom chemotherapy can be safely spared.

### 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® test, is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score® test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention, and the Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego and offered exclusively by Genomic Health. With more than 1 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 tests, visit [www.OncotypeIQ.com](http://www.OncotypeIQ.com), [www.MyBreastCancerTreatment.org](http://www.MyBreastCancerTreatment.org) or [www.MyProstateCancerTreatment.org](http://www.MyProstateCancerTreatment.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 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 over 1 million cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the 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](http://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 Oncotype DX Breast Recurrence Score test to physicians, patients and payors; the results of the TAILORx study including secondary analysis and its implications on clinical treatment decisions; the ability of the Oncotype DX Breast Recurrence Score test to improve patient outcomes; and the ability of the company to achieve additional global reimbursement coverage for its Oncotype DX Breast Recurrence Score test, including in Germany. 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; 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 quarterly report filed on Form 10-Q for the quarter ended June 30, 2019. 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, Oncotype, Oncotype DX, Breast Recurrence Score, DCIS Score, Genomic Prostate Score, GPS, Oncotype DX 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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<sup>1</sup> Sparano et al. *Jama Oncology*. 2019.

<sup>2</sup> European Society for Medical Oncology.

<sup>3</sup> Paik et al. *JCO*. 2006.



