



Updated ASCO Guidelines Establish TAILORx-defined Cutoffs for Determining Chemotherapy Benefit with the Oncotype DX Breast Recurrence Score® Test in Node-negative Breast Cancer

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New ASCO Recommendations Increase Proportion of Women Who Can Be Spared Chemotherapy Based on Landmark TAILORx and NSABP B-20 Randomized Clinical Trials

Additional Secondary Analysis of TAILORx Trial to be Presented at ASCO Annual Meeting Today

REDWOOD CITY, Calif., June 3, 2019 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced that its Oncotype DX Breast Recurrence Score® test and the TAILORx results have been recommended to guide chemotherapy treatment use in patients with node-negative early-stage breast cancer by the American Society of Clinical Oncology (ASCO) in its [2019 Guidelines for Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy](#). Using the strong and highest level of evidence from TAILORx, the updated ASCO guidelines increase the proportion of women who can be effectively treated without chemotherapy based on the Oncotype DX® results, highlighting the importance of testing all medically eligible patients as standard of care.

"We are pleased that the ASCO guidelines have been updated to reflect the findings from the landmark TAILORx trial, the practice-changing results of which demonstrated that the Oncotype DX Recurrence Score result can be used to guide chemotherapy decision-making for all medically eligible women with the most common form of early-stage, invasive breast cancer," said Steven Shak, M.D., chief scientific officer, Genomic Health. "The TAILORx results have influenced positive treatment guideline recommendations from ASCO and other organizations around the world, elevating the Oncotype DX test to a new global standard of care."

TAILORx, sponsored by the National Cancer Institute (NCI) and conducted by the ECOG-ACRIN Cancer Research Group, involved 10,273 women across 1,100 trial sites in six participating countries. The study results, which were presented during the Plenary Session at the 2018 ASCO Annual Meeting last June and simultaneously published in [The New England Journal of Medicine](#), demonstrated that the Oncotype DX Breast Recurrence Score test definitively identifies the vast majority of women with early-stage breast cancer who receive no benefit from chemotherapy, and the important minority of women for whom chemotherapy benefit can be life-saving. Patients with an Oncotype DX Breast Recurrence Score result of 25 or less – up to about 80 percent of patients – may be safely spared chemotherapy and its well-known side effects, while those with scores of 26 to 100 may receive a life-saving benefit from chemotherapy.

"The updated ASCO breast cancer treatment guidelines based on the TAILORx results will provide physicians with clarity and confidence that they are selecting the right treatment for each of their breast cancer patients," said Harold A. Burstein, M.D., Ph.D., medical oncologist at the Dana-Farber Cancer Institute. "Having guidelines that reflect the latest ground-breaking research is critical in ensuring that physicians incorporate standard-of-care technology, such as the Oncotype DX test, when making clinical decisions about treatment for their patients with breast cancer."

New TAILORx Data Analysis at 2019 ASCO Annual Meeting

New analysis of a secondary endpoint of the TAILORx trial will be presented in the "Breast Cancer—Local/Regional/Adjuvant" oral abstract session at the 2019 ASCO Annual Meeting. The presentation, titled "Impact of clinical risk category on prognosis and prediction of chemotherapy benefit in early breast cancer (EBC) by age and the 21-gene recurrence score (RS) in TAILORx," will take place on Monday, June 3. The abstract (#503) can be accessed [here](#).

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, www.MyBreastCancerTreatment.org or 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 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 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 expand commercial access and increase utilization of its Oncotype DX Breast Recurrence Score test. 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 annual report filed on Form 10-Q for the year ended March 31, 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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