New Long-term Outcomes Data Presented at St. Gallen International Breast Cancer Conference Reinforce TAILORx Treatment Paradigm and Standard of Care Use for Oncotype DX Breast Recurrence Score® Test

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Importance of tailoring chemotherapy use and differences between tests acknowledged by leading international breast cancer specialists

REDWOOD CITY, Calif., March 25, 2019 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced that new data presented at the 16th St.Gallen International Breast Cancer Conference in Vienna reinforce the utility of the Oncotype DX Breast Recurrence Score® test to optimize chemotherapy recommendations in patients with early-stage breast cancer with or without lymph node involvement.

The important role of genomic testing to optimize patient outcomes in early-stage breast cancer was discussed in a debate between leading international breast cancer specialists during the St. Gallen Conference. The experts presented several case studies showing that genomic testing adds value beyond clinical pathological factors, and they agreed that there are substantial differences between the available tests.

"Only a test such as Oncotype DX that has been developed specifically to be predictive of chemotherapy benefit can identify the right treatment for the right patient," said Prof. Joseph Gligorov, M.D., of the Breast Cancer Expert Center at the APHP-Tenon Hospital in Paris, who participated in the panel discussion. "The practice-changing precision made possible by such a test can lead to improved quality of care and survival among breast cancer patients, as well as reduced waste of healthcare resources by directing chemotherapy only to patients who have a high likelihood of deriving substantial benefit."

Oncotype DX Data Presentations

An updated analysis of the Clalit Health Services registry, the largest health services organization in Israel, was presented at the Conference. This analysis examined the medical records of more than 1,300 patients with node-negative breast cancer applying the Recurrence Score cut point determined by the landmark TAILORx study. The findings showed that use of chemotherapy was aligned with Oncotype DX test results and that patients with Recurrence Score results up to 25, the vast majority of whom were treated with hormonal therapy alone, had excellent outcomes at 10 years, with low rates of distant recurrence.

Also presented at the Conference was real-world evidence from a study in more than 80,000 patients, based on an analysis of data from the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI). The findings confirmed that the Recurrence Score result is predictive of chemotherapy benefit in patients with node-negative disease (p=0.009), with no chemotherapy benefit in patients with Recurrence Score results up to 25. In patients with node-negative disease and Recurrence Score results up to 25 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 Recurrence Score results less than 18, BCSS was greater than 97 percent at nine years.

Importantly, this real-world evidence reinforces the paradigm established by the TAILORx study, which provided definitive information on how to treat women with node-negative early-stage breast cancer based on their Recurrence Score results. TAILORx, the largest randomized adjuvant breast cancer treatment trial ever conducted, identified the vast majority of women who receive no substantial benefit from chemotherapy, as well as the important minority for whom chemotherapy can be life-saving.

Results of two decision impact studies from the UK and the Czech Republic, highlighting the value of Oncotype DX to personalize and improve the quality of clinical decisions, also were presented at the Conference. In the UK study, clinical practice results from 582 patients with node-positive disease (one to three positive lymph nodes) showed that chemotherapy recommendations changed in a significant proportion of patients following testing with Oncotype DX. In particular, the test allowed more than 60 percent of patients to be spared chemotherapy and its associated short- and long-term side-effects. Conversely, the test identified 23 patients who were initially advised to undergo only endocrine therapy, but whose treatment was changed to add chemotherapy based on their Recurrence Score result. Without testing, these patients would not have received potentially life-saving chemotherapy treatment.

"In serving more than one million cancer patients around the world with Oncotype DX, we are delivering on the promise of precision medicine by improving outcomes, while saving healthcare systems around the world billions of dollars," said Rick Baehner, M.D., chief medical officer, Genomic Health. "These new data, based on results from thousands of patients in the U.S. and Europe, further reinforce the value and need for broader global access to Oncotype DX testing."

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.MyProstateCancerTreatement.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 belief that the Oncotype DX Breast Recurrence Score test is unique in its ability to predict chemotherapy benefit in early-stage breast cancer; the company's belief that the Oncotype DX Breast Recurrence Score test is cost-effective and can reduce the cost of treatment in health systems around the world; the applicability of study results to actual outcomes; and the ability of the company's tests to impact clinical practice. 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 company's ability to increase usage of its tests; the company's ability to successfully commercialize its testsglobally ; the company's ability to compete against third parties; 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 and uncertainties associated with regulation of the company's tests; 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 Quarterly Report on Form 10-K for the year ended December 31, 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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