New Analysis of NSABP Randomized B-20 Study Confirms Patients with Oncotype DX Breast Recurrence Score® Results Greater Than 25 Have Life-saving Benefit from Chemotherapy, Reinforcing the Conclusions of the Landmark TAILORx Study

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Published Results Underscore Value of Oncotype DX® Test in Identifying Women with Early-stage Breast Cancer Who May Receive Life-saving Benefit from Chemotherapy

REDWOOD CITY, Calif., Nov. 29, 2018 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) and the NSABP Foundation today announced the publication of positive results from a new analysis of the NSABP-led B-20 study reconfirming that the Oncotype DX Breast Recurrence Score® test predicts which patients with early-stage, HER2-negative breast cancer will benefit from chemotherapy.

Applying the patient criteria from the TAILORx study, the largest ever breast cancer treatment trial, sponsored by the National Cancer Institute (NCI), and led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN), NSABP conducted a new analysis in 569 patients from its previously completed B-20 study. The results show that Oncotype DX® provides definitive information about which patients will derive life-saving benefit from chemotherapy treatment.

"We previously had an unprecedented amount of data on patients with Oncotype DX Breast Recurrence Score results of 25 or lower, and now with the results from TAILORx and the new B-20 analysis, we have critical confirmation for patients with scores over 25 that they should be treated with chemotherapy," said Norman Wolmark, M.D., chairman of the NSABP Foundation in Pittsburgh, Pennsylvania. "Our publication underscores the important clinical value of the Oncotype DX test in guiding treatment decision in every early-stage, HER2-negative breast cancer patient."

The new results, published in November in the Nature Partner Journals (NPJ) Breast Cancer, show a statistically significant (p<0.001) benefit from the addition of chemotherapy to hormonal therapy in patients with Breast Recurrence Score results greater than 25.

About 50 percent of all breast cancer patients diagnosed worldwide each year have hormone-receptor positive, HER2-negative, node-negative cancer. The TAILORx study, published in The New England Journal of Medicine, definitively established that chemotherapy may be spared in the majority of these patients. Importantly, some early-stage breast cancer patients – as reinforced by the new NSABP publication - will derive life-saving benefit from chemotherapy, including women with Breast Recurrence Score® results of 26 to 100. TAILORx participants with Breast Recurrence Score results from 26 to 100 were treated with chemotherapy plus endocrine therapy.

"The new B-20 study analysis, combined with the published results from TAILORx, provide unparalleled evidence from randomized patients that Oncotype DX can predict which patients will benefit from chemotherapy," said Steven Shak, M.D., chief scientific officer and chief medical officer, Genomic Health. "Also recognized by the National Comprehensive Cancer Network (NCCN) as the only multi-gene test to predict chemotherapy benefit, physicians can now tell every patient more confidently, based on Oncotype DX, whether they should receive chemotherapy or not."

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 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 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, 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 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, 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. 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 Quarterly Report on Form 10-Q for the quarter 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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