Secondary Analysis of Landmark TAILORx Results, Published Today in The New England Journal of Medicine, Affirms Unique Ability of Oncotype DX Breast Recurrence Score® to Predict Chemotherapy Benefit, Guiding Adjuvant Therapy with Even Greater Precision

June 3, 2019

Additional Detail in Patients Age 50 or Younger Presented Today in Oral Session at 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

TAILORx Continues to Elevate Oncotype DX® to a New Global Standard with Increasing Utilization and Reimbursement

REDWOOD CITY, Calif., June 3, 2019 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced that results from a new analysis of the Trial Assigning IndividuaLized Options for Treatment (Rx), or TAILORx, confirm the original, definitive conclusions reported last year with additional detail on clinical risk, focusing on patients with early-stage breast cancer who are age 50 years or younger. These findings, published today in *The New England Journal of Medicine* and presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, showed that stratifying patients by clinical risk (tumor size and histologic grade) alone does not predict chemotherapy benefit. Clinical risk provides prognostic information that is complementary to the Oncotype DX Breast Recurrence Score® test and may help identify younger women who benefit from more effective therapy.

"We're pleased to see leading authorities, including *TheNew England Journal of Medicine* and ASCO, continue to recognize the significant results and impact of TAILORx one year after it established that Oncotype DX 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," said Steven Shak, M.D., chief scientific officer, Genomic Health. "The additional insight from this new analysis confirms young women with breast cancer are not all the same and indicates that they should be treated individually based on the biology of their disease, as determined by Oncotype DX and an assessment of their clinical risk."

A secondary objective 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 whether clinical risk provides additional prognostic or predictive information to the Recurrence Score (RS) results. Of 9,427 women in TAILORx with a RS and clinical risk information, 70 percent were determined to be low clinical risk (tumor ≤3 cm and low grade, ≤2 cm and intermediate grade, or ≤1 cm and high grade) and 30 percent were identified as high clinical risk (not meeting low clinical risk criteria). While clinical risk provided additional prognostic information across all RS groups, disease-free survival and distant recurrence-free interval rates were similar with and without chemotherapy in the entire RS 11-25 group irrespective of clinical risk.

"Last year, TAILORx established the highest level of evidence and unprecedented precision supporting use of the Oncotype DX Breast Recurrence Score 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. "With this new analysis, it is clear that women age 50 or younger with a Recurrence Score result between 16 and 20 and low clinical risk do not need chemotherapy. Furthermore, Oncotype DX in combination with clinical risk factors could identify premenopausal women with higher clinical risk who may benefit from ovarian function suppression and more aggressive anti-estrogen therapy."

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*, are elevating Oncotype DX to a new global standard of care with increasing, and more consistent, use of Oncotype DX by physicians worldwide for all medically eligible patients. Additionally, important guidelines globally distinguish Oncotype DX from other prognostic-only tests based on clinical evidence and the critical importance of predicting chemotherapy benefit. This includes the recent update to ASCO guidelines, which increased the proportion of women who can be effectively treated without chemotherapy based on the strong and highest level of evidence from TAILORx, as well as National Comprehensive Cancer Network (NCCN) guidelines, which were updated last fall to categorize Oncotype DX as the only "preferred" test for chemotherapy treatment decision-making for patients with node-negative early-stage breast cancer. The landmark TAILORx study is also having an important impact on global reimbursement of Oncotype DX, including in Germany. Following the German Institute for Quality and Efficiency in Health Care's (IQWiG's) positive assessment, the German Federal Joint Committee (G-BA) is expected to make a decision on Oncotype DX reimbursement at its plenary meeting on June 20.

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 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 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.

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Investors & Media, Emily Faucette, Genomic Health, 650-569-2824, investors@genomichealth.com, media@genomichealth.com