Landmark TAILORx Results Aid in Assessing the Effect of Chemotherapy in Women with Early-stage Breast Cancer and Oncotype DX Breast Recurrence Score® Results of 11 to 25

Results from Large, Prospective Randomized Clinical Trial to be Submitted for Presentation at Upcoming Major Medical Meeting

REDWOOD CITY, Calif., March 15, 2018 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) was informed by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) that the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, has achieved sufficient information to render a conclusion regarding the effect of chemotherapy in early-stage breast cancer patients with Recurrence Score® results of 11 to 25. This primary study group represents approximately 100,000 women diagnosed each year in the United States alone. ECOG-ACRIN will be submitting the results as a late-breaking abstract for presentation at an upcoming major medical meeting.

The TAILORx trial was independently designed and conducted by ECOG-ACRIN under the sponsorship of the National Cancer Institute (NCI), part of the National Institutes of Health. The primary objective of TAILORx is to more precisely determine the effect of chemotherapy, if any, for women with node-negative, hormone receptor-positive disease and Oncotype DX Breast Recurrence Score® results of 11 to 25.

TAILORx is the largest adjuvant breast cancer treatment trial ever conducted, and enrolled 10,273 women with early-stage breast cancer across approximately 1,200 sites in the United States and five additional countries. Investigators used the Oncotype DX Breast Recurrence Score test on every patient to quantify individual risk of recurrence and assign treatment to determine whether chemotherapy would be beneficial or not. Based on previous studies, TAILORx participants with Recurrence Score results less than 11 were treated with hormonal therapy alone while those with Recurrence Score results greater than 25 were treated with chemotherapy plus hormonal therapy.

To more precisely define the effect of chemotherapy for women considered to be at intermediate risk for recurrence, more than 6,700 women with Oncotype DX Breast Recurrence Score results of 11 to 25, the primary study group, were randomized to receive hormonal therapy with or without chemotherapy. These randomized patients comprised 65 percent of all TAILORx patients and were followed for approximately nine years on average. All five adult cancer research groups in the NCI's National Clinical Trials Network (NCTN) enrolled patients in the trial. These groups include ECOG-ACRIN, the Alliance for Clinical Trials in Oncology, NRG Oncology, SWOG and the Canadian Cancer Trials Group. Leading breast cancer advocacy organizations, including the Breast Cancer Research Foundation, Susan G. Komen and the National Breast Cancer Coalition, also supported the trial.

"We are proud that the Oncotype DX Breast Recurrence Score test played a pivotal role in assigning treatment for this pioneering precision medicine trial. These TAILORx results will more precisely inform physicians and their patients with Recurrence Score results of 11 to 25 about who will, or will not, benefit from the addition of chemotherapy," said Steven Shak, M.D., chief scientific officer, Genomic Health.

In 2015, results from the TAILORx secondary study group with Oncotype DX Breast Recurrence Score results less than 11 were published in The New England Journal of Medicine. More than 99 percent of the 1,626 women who received hormonal therapy alone without chemotherapy were free of breast cancer distant recurrence after five years. These results provided the highest level of evidence (level 1A) supporting the clinical utility of Oncotype DX® to identify early-stage breast cancer patients who can safely avoid chemotherapy treatment.

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. With more than 850,000 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.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 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 850,000 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; 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-K for the year ended December 31, 2017. 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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