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Genomic Health Announces Multiple Studies Reinforcing Value of Oncotype DX® Tests in Guiding Treatment for Breast and Prostate Cancer Patients

Studies Presented at ESMO 2018 Congress Underscore Growing Clinical Evidence Across Genomic Health's Test Portfolio

REDWOOD CITY, Calif., Oct. 22, 2018 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from multiple studies of its Oncotype DX® tests highlighting their value in optimizing treatment for patients with various stages of breast and prostate cancer. The findings, presented at the ESMO 2018 Congress in Munich, Germany, demonstrated that the Oncotype DX tests identify patients who will or will not benefit from a specific treatment.

Underscoring the growing international impact of the Oncotype DX Breast Recurrence Score® test, two European-based studies involving patients from Ireland, France and Italy demonstrated its impact on treatment decisions for women with node-negative and node-positive breast cancer. Additionally, three prostate cancer studies in the United States demonstrated how the Oncotype DX Genomic Prostate Score® (GPS™) and AR-V7 Nucleus Detect™ tests refine treatment decisions in men with clinically low-intermediate risk or metastatic prostate cancer based on the aggressiveness of their tumor or their resistance to androgen receptor (AR)-targeted drugs.

"Oncotype DX tests have contributed to precision medicine in breast cancer for nearly 15 years, and there is now a growing body of evidence for their predictive value and clinical utility in guiding treatment selection for men with early-stage, as well as metastatic prostate cancer," said Steven Shak, M.D., chief scientific and medical officer, Genomic Health.

Oncotype DX in Node-negative and Node-positive Breast Cancer
In Ireland, researchers assessed the impact of the Oncotype DX Breast Recurrence Score on treatment decisions in routine clinical practice for early-stage breast cancer patients whose disease had spread to one to three lymph nodes (Poster #208P). Results showed that oncologists believed the test significantly changed their treatment recommendations 64 percent of the time, and that use of the Oncotype DX® test led to a 27 percent reduction in recommendations for chemotherapy.

Additionally, results from a real-life, decision-impact study of breast cancer patients in France and Italy, including those with node-negative and node-positive disease, showed that treatment recommendations changed in 35 percent of patients based on their Oncotype DX test results (Poster #194P). This resulted in a 43 percent reduction in chemotherapy recommendations.

Importantly, in each country, the Oncotype DX Breast Recurrence Score result, when high, also identified the minority of patients for whom chemotherapy is potentially life-saving, highlighting the distinctive predictive value that only the Oncotype DX test delivers.

"These new results strengthen published findings from our PlanB study and show the unique value of adding genomic information provided by the Oncotype DX test to better target chemotherapy. Oncotype DX identifies patients who can safely be spared chemotherapy toxicity and side effects. Furthermore, we have to be concerned about a relevant proportion of patients who seem to be undertreated if the risk of recurrence is evaluated using only traditional clinical parameters," said Prof. Ulrike Nitz, head of the breast cancer/senology unit at the Bethesda Hospital, Moenchengladbach, Germany. "The use of the Oncotype DX test allows us to tailor treatment plans more accurately to suit the needs of individuals, and to use resources more effectively."

Oncotype DX Optimizes Treatment in Early-stage and Metastatic Prostate Cancer
Based on results from a published study, the Center for Prostatic Disease Research (CPDR) of the Uniformed Services University of the Health Sciences conducted additional analysis of the Oncotype DX Genomic Prostate Score test results in 395 men with clinically low, and intermediate-risk prostate cancer (Poster #837P). Results demonstrated that the GPS test was a significant, independent predictor of increased risk of biopsy upgrade in these patients. These data add to a separate recent independent study published by the University of California, San Francisco (UCSF) and underscore the value of the GPS test in identifying patients with more aggressive tumor biology who should be more aggressively treated at diagnosis.

The Oncotype DX GPS test is the only genomic assay designed for men at the time of diagnosis with clinically low-risk or favorable intermediate-risk cancer to help make treatment decisions based on their likelihood of adverse pathology. Developed by Genomic Health, based on results from multiple studies led by Cleveland Clinic and UCSF, the GPS test optimizes treatment by providing physicians with an assessment of both the current status (adverse pathology) and future risk (metastasis and mortality) of a patient's cancer in making confident treatment decisions regarding active surveillance versus immediate aggressive treatment.

In metastatic prostate cancer, presentations included two studies of the Oncotype DX AR-V7 Nucleus Detect, a CTC-based, liquid biopsy test that helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant, or not, to AR-targeted therapies, such as enzalutamide and abiraterone, and which patients may benefit from chemotherapy. The Oncotype DX AR-V7 Nucleus Detect test is commercially available in the United States through Epic Science's collaboration with Genomic Health.

A new analysis, combining data from two published studies, confirmed that the Oncotype DX AR-V7 Nucleus Detect test for AR-V7 protein is a predictive biomarker for identifying patients who will not respond to additional AR-targeted therapy (Poster #848P). These data further support that detection of nuclear-localized AR-V7-positive circulating tumor cells (CTCs) by the Oncotype DX test indicates that the patient will not benefit from additional treatment with commonly-prescribed AR-targeted therapy and should consider switching to an alternative therapy to increase survival.

Separately, an independent study of the Oncotype DX AR-V7 Nucleus Detect test conducted by Epic Sciences in collaboration with its academic partners confirmed that the use of AR-V7 optimizes therapy guidance over risk assessment alone (Poster #836P).

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 900,000 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.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 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 900,000 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 results of clinical studies; the impact of clinical studies on reimbursement and test adoption; the applicability of clinical study results to actual outcomes; the commercial performance of the company's tests; and the benefits of the 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 risk that the company may not obtain or maintain adequate levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the ability of the company to achieve expanded coverage of reimbursement for its existing tests and the ability of any such expanded coverage to result in additional revenue; the ability of test results to change treatment decisions; the risks of competition; the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes and the ability to demonstrate sufficient clinical utility;

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 our most recent report on Form 10-Q for the quarter ended June 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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