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Oncotype DX® Breast Cancer Cancer Test Predicts Late Recurrence Five to 15 Years Out

New Data Presented at ASCO® Annual Meeting Suggest that Genomic Health's Oncotype DX Test May Help Identify Patients That Have the Greatest Opportunity to Benefit from Extended Hormonal Therapy

REDWOOD CITY, Calif., May 29, 2014 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results of a large, positive study that confirmed that the Oncotype DX® test results for Recurrence Score® and quantitative estrogen-receptor (ER) predict late distant recurrence risk in early-stage breast cancer patients after initial tamoxifen therapy, suggesting that Oncotype DX may help identify which patients have greater potential to benefit from extended hormonal treatment beyond five years. One of the nine Oncotype DX studies being presented at the 2014 American Society of Clinical Oncology® (ASCO®) Annual Meeting taking place in Chicago, these data will be presented on June 2 at 8:00 a.m. Central Time.

"As recognized by ASCO's guideline update, recent studies have shown that extending tamoxifen treatment for 10 years is associated with better outcomes, however, we still need better tools to identify who those patients are," said Norman Wolmark, M.D., chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP). "This study confirms that Oncotype DX can help better define who is at greatest risk for late recurrences and the potential to benefit from extended tamoxifen, as well as those who are at lower risk and will likely have less absolute benefit from extended tamoxifen and, thus, could be spared prolonged exposure and risk of long-term side effects."

This new study analyzed 668 and 1065 patients from the original NSABP B-14 and B-28 trials, respectively. Median follow-up of 13.9 years (B-14) and 11.2 years (B-28) determined that the Oncotype DX Recurrence Score results were significantly associated with distant recurrence after five years in patients whose tumors had high estrogen receptor expression. Specifically, in the NSABP B-14 patients, the association of the continuous Recurrence Score with distant recurrence after five years in the higher ER patients was significant (p=0.004) after adjustment for age, grade and tumor size. The results suggest that extending tamoxifen beyond five years may be most beneficial in patients with high and intermediate Recurrence Scores with higher quantitative ER expression. Conversely, patients with low Recurrence Score results would be expected to have limited benefit from extended tamoxifen beyond five years due to much lower risk for late distant recurrence.

"Since its introduction a decade ago, the Oncotype DX breast cancer test has helped patients and their physicians around the world make better informed treatment decisions," said Phil Febbo, M.D., chief medical officer, Genomic Health. "These new data emphasize our ability to guide breast cancer treatment decisions throughout the patient's cancer journey, addressing additional questions to make cancer care smarter."

Future announcements will highlight results from additional Oncotype DX studies in breast, prostate and renal cancers, demonstrating the unique, practice-changing impact of the Oncotype DX tests worldwide.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early stage cancer, one of the greatest issues in healthcare today. The company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of massive amounts of genomic data into clinically-actionable results for treatment planning throughout the cancer patient's journey, from screening and surveillance, through diagnosis, treatment selection and monitoring. Genomic Health's lead product, the Oncotype DX® breast cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer and has been shown to predict the likelihood of recurrence in ductal carcinoma in situ (DCIS). In addition to this widely adopted test, Genomic Health provides the Oncotype DX colon cancer test, the first multi-gene expression test developed for the assessment of risk of recurrence in patients with stage II and stage III disease, and the Oncotype DX prostate cancer test, which predicts disease aggressiveness in men with low risk disease. As of March 31, 2014, more than 19,000 physicians in over 70 countries had ordered more than 440,000 Oncotype DX tests. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth. To learn more about OncotypeDX tests, visit: www.OncotypeDX.com, www.mybreastcancertreatment.org and www.myprostatecancertreatment.org.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the company's intent to continue its investment to capture significant opportunities in the international and prostate markets; the company's expectations regarding reporting study results; the attributes and focus of the company's product pipeline; the applicability of clinical study results to actual outcomes; the ability of any potential tests the
company may develop to optimize cancer treatment; and the ability of the company to develop and commercialize additional tests in the future. 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 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; our ability to develop and commercialize new tests and expand into new markets domestically and internationally; 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; the company’s ability to obtain capital when needed 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 report on Form 10-Q for the period ended March 31, 2014. 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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