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Genomic Health Announces Positive Topline Results of Large Prostate Cancer Clinical Validation Study; Company to Proceed with 2013 Commercial Launch

- Complete Data to be Submitted for Presentation at the 2013 ASCO Genitourinary Cancers Symposium -

REDWOOD CITY, Calif., Sept. 18, 2012 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced positive results from a large clinical validation study of its biopsy-based prostate cancer test. The study, performed in collaboration with leading prostate cancer researchers at the University of California, San Francisco (UCSF), met its primary endpoint by demonstrating that the multi-gene *Oncotype DX*® Genomic Prostate Score (GPS), assessed in prostate needle biopsy tumor tissue, has been prospectively validated as a predictor of adverse pathology for patients with early-stage prostate cancer. UCSF and Genomic Health plan to submit complete data from this study for presentation at the 2013 ASCO Genitourinary Cancers Symposium in February. Based on these results, Genomic Health is completing the necessary work in its Clinical Reference Laboratory to make the *Oncotype DX* prostate cancer test available to physicians and patients in the first half of 2013.

"It is widely recognized that a very large percentage of men with low and intermediate risk prostate cancer are over-treated due in part to the lack of a standardized, validated biopsy-based test to more accurately distinguish between aggressive and clinically indolent disease," said Peter Carroll, M.D., M.P.H., Chair, Department of Urology, University of California, San Francisco. "These results have the potential to change medical practice significantly by providing physicians and their patients with a multi-gene prostate cancer test, designed specifically for biopsies, that will improve treatment decisions for early-stage prostate cancer at the time of diagnosis."

As was the case for the established *Oncotype DX* breast and colon cancer tests, Genomic Health and its collaborators used a rigorous clinical development strategy for development and validation of the *Oncotype DX* Genomic Prostate Score. In a three year effort, Genomic Health optimized its proprietary RT-PCR methodology to be able to analyze the very small amounts of formalin-fixed paraffin-embedded prostate tissue obtained by diagnostic prostate needle biopsies.

"The over-treatment of prostate cancer represents one of the most significant issues in men's health today," said Howard Soule, Executive Vice President and Chief Science Officer of the Prostate Cancer Foundation. "With this study, Genomic Health has applied its groundbreaking technology and innovative clinical trial expertise to address a critical treatment decision facing hundreds of thousands of men each year."

Genomic Health conducted six feasibility and development studies in collaboration with the Cleveland Clinic evaluating more than 700 patients and 700 candidate genes to select the genes for this test. The resulting pre-specified test was then evaluated in prostate needle biopsy specimens in the prospectively-designed UCSF clinical validation study. It is expected that in conjunction with the Gleason grading system and conventional parameters such as PSA, age, and physical examination, the *Oncotype DX* Genomic Prostate Score will be utilized to personalize prostate cancer treatment based on the underlying biology of an individual patient's tumor.

"Each year in the U.S. alone, more than 240,000 men are diagnosed with prostate cancer, with the vast majority receiving aggressive treatments associated with serious, long-term side effects. Based on the results of this study, we believe the *Oncotype DX* Genomic Prostate Score will increase the number of patients eligible for active surveillance, and identify those who should consider aggressive treatment," said Steven Shak, Executive Vice President of Research and Development and Chief Medical Officer at Genomic Health. "With our proven record of developing and validating multi-gene tests, combined with our established global infrastructure, we believe Genomic Health is well positioned to deliver this critical tool to physicians and prostate cancer patients around the world."

About Genomic Health

[Genomic Health](#), Inc. (NASDAQ: GHDX) is a global health company that provides actionable genomic information to personalize genomic health decisions. The company'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 disease and appropriate stage III patients. As of June 30, 2012, more than 10,000 physicians in over 65 countries had ordered more than 300,000 *Oncotype DX* tests. Genomic Health has a robust pipeline focused on developing tests to optimize the treatment of prostate and renal cell cancers, as well as additional treatment decisions in breast and colon cancers. The

company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com. To learn more about Oncotype DX tests, visit: www.OncotypeDX.com and www.mybreastcancertreatment.org.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our plans to analyze, submit and present the complete data from this study at the 2013 ASCO Genitourinary Cancers Symposium; the expectation that top line study results will be confirmed in the complete analysis of the study data; our plans to commercially launch an Oncotype DX test for prostate cancer in the first half of 2013; the ability of any such test to individualize cancer treatment decisions for prostate cancer patients at the time of diagnosis; the potential of the test to change medical practice for some prostate cancer patients; the ability of the company to develop additional tests in the future; the scope, success or results of clinical trials and the timing of such activities; the applicability of clinical study results to actual outcomes; the ability of the test to impact clinical practice; the ability of the company to obtain and maintain adequate reimbursement for the test; our beliefs regarding the attributes of our product pipeline; and our ability to develop 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 results of clinical studies; the applicability of clinical study results to actual outcomes; the risks and potential delays associated with such studies; the risks, costs and potential delays associated with the commercialization of current and future products; unanticipated costs or delays in research and development efforts; risks and uncertainties associated with the regulation of and reimbursement for our tests, both domestically and abroad; our ability to compete against third parties; 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 June 30, 2012. 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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