Oncotype DX® Genomic Prostate Score® Established as First Genomic Test with Prospective Validation for Predicting Adverse Pathology in Newly Diagnosed Patients

February 5, 2019

Results, Published in Urology, Represent First Prospective Validation of Critical Endpoint to Identify Patients for Active Surveillance

REDWOOD CITY, Calif., Feb. 5, 2019 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced the publication of results from a multi-center, prospective validation study of the Oncotype DX® Genomic Prostate Score® (GPS ™) test in newly diagnosed men with clinically low-risk prostate cancer who elected immediate radical prostatectomy after receiving the test. Published in *Urology*, the study results prospectively validated the GPS test as an independent predictor of adverse pathology at the time of surgery as a measure of disease aggressiveness for men with clinically low- or intermediate-risk prostate cancer.

"These positive results represent the third published validation study of the Oncotype DX GPS test to predict adverse pathology at the time of radical prostatectomy, as well as the first truly prospective validation of this critical endpoint," said Steven Shak, M.D., chief scientific officer, Genomic Health. "In providing more precise estimates of disease aggressiveness beyond clinical factors, the GPS test can help physicians potentially increase the number of men who are eligible and appropriate for active surveillance, while identifying men with more aggressive disease who may consider immediate surgical treatment with more confidence."

The prospective study enrolled 1,200 men with very low-, low- and favorable intermediate-risk prostate cancer between July 2014 and September 2015 at 26 community-based urology practices in the United States. A total of 114 men (from 19 sites and 59 treating physicians) who proceeded to immediate radical prostatectomy after GPS testing as initial management were included in a pre-specified analysis.

These new prospective findings reinforce the results of two independent published studies based on retrospective patient cohorts. Collectively, these published studies clearly demonstrate that the Oncotype DX GPS test provides critical information that guides decision making in early-stage prostate cancer.

The study also assessed the effect of GPS testing on physicians' and patients' attitudes about decision making using the Decisional Conflict Scale (DCS). Results showed that GPS testing increased physician confidence and decreased decision conflict in patients who elected radical prostatectomy as initial management. Specifically, 90 percent of both physicians and patients reported that GPS testing was useful as a source of increased confidence for physicians and for decision making by patients.

"Determining the optimal treatment for patients with localized prostate cancer that has not metastasized depends on accurate risk assessment," said David M. Albala, M.D., chief of urology, Crouse Hospital in Syracuse, N.Y. "This study is important because it validated the GPS test in a prospectively enrolled contemporary cohort of men and was conducted among geographically diverse, large community practices. The findings indicate that Oncotype DX testing can give physicians increased confidence in their decision-making process and provide low-risk prostate cancer patients with greater certainty about their chosen management strategy, empowering them to make effective choices regarding their care."

About the Oncotype DX® Genomic Prostate Score® (GPS ™) Test

Developed by Genomic Health based on results from multiple studies led by Cleveland Clinic and the University of California, San Francisco, the Oncotype DX® GPS test is the only genomic assay designed for men with clinically low-risk or favorable intermediate-risk cancer to help make treatment decisions at the time of diagnosis. The test analyzes 17 genes across four biological pathways from tumor tissue removed during biopsy to provide a GPS result with a score ranging from 0-100 that corresponds to the biologic aggressiveness of the tumor and the patient's likelihood of prostate cancer metastasis and death at 10 years. The GPS test is included within NCCN Guidelines® as a Category 2A molecular testing option for consideration in prostate cancer patients with clinically low-risk and favorable intermediate-risk disease and is covered by Medicare and multiple private insurance companies in the United States. To learn more about the Oncotype DX Genomic Prostate Score test, visit www.OncotypeIQ.com 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 1 million 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 inRedwood 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 Oncotype DX tests 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

GHDX-P

View original content to download multimedia:http://www.prnewswire.com/news-releases/oncotype-dx-genomic-prostate-score-established-as-first-genomic-test-with-prospective-validation-for-predicting-adverse-pathology-in-newly-diagnosed-patients-300789470.html

SOURCE Genomic Health, Inc.

Investors: Emily Faucette, Genomic Health, 650-569-2824, investors@genomichealth.com; Media: Victoria Steiner, Genomic Health, 415-370-5804, media@genomichealth.com