

May 21, 2018

New Data Reinforce Positive Impact of the Oncotype DX® Genomic Prostate Score™ Test in Guiding Treatment Decisions

Studies in Over 30,000 Newly Diagnosed Prostate Cancer Patients Presented at American Urological Association (AUA) Annual Meeting Confirm Utility of GPS™ Test in Optimizing Cancer Care

REDWOOD CITY, Calif., May 21, 2018 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results from two new studies demonstrating the positive impact of the Oncotype DX[®] Genomic Prostate Score™ (GPS™) test on risk assessment for better treatment decisions in clinically low-risk prostate cancer patients in real-world practice. The data were presented at the 2018 American Urological Association (AUA) Annual Meeting in San Francisco, May 18-21.

"The study results presented at AUA are remarkably consistent with previously published clinical utility studies, which clearly demonstrate the value of the Oncotype DX Genomic Prostate Score test in predicting future risk to enable more informed treatment decisions at diagnosis," said Steven Shak, M.D., chief scientific officer and chief medical officer, Genomic Health. "The new data showing greater use of active surveillance and persistence on active surveillance further support our efforts to expand patient access and private reimbursement in the U.S. this year."

GPS Test Improves Risk Assessment for One in Four Patients

An analysis performed on the first 29,000 Oncotype DX GPS tests performed in the Genomic Health Clinical Laboratory showed that the test refined patient risk for approximately one in four men (26 percent) across studied NCCN risk groups. The largest shift in risk assessment in men (50 percent) was observed among NCCN low-risk patients. Of those who were reclassified, 35 percent had more favorable biology consistent with very-low risk, and 15 percent had less favorable biology consistent with intermediate risk.

"Our experience from tens of thousands of prostate cancer patients confirms that the Oncotype DX GPS test provides critical new information based on the unique biology of an individual man's cancer compared to current NCCN clinical risk groups alone," said Aaron Katz, M.D., chairman, Department of Urology, Winthrop-University Hospital, New York. "By enabling more precise risk assessment, the GPS test helps physicians more confidently optimize treatment decisions in men with clinically low-risk disease."

Prospective Study Results Demonstrate GPS Test Changes Clinical Management for One in Four Men and is Associated with High Persistence on Active Surveillance at One Year

A prospective, observational study of 1,200 men conducted in 26 community urology practices evaluated the impact of the GPS test on management decisions and persistence on active surveillance. One-year results from 770 patients demonstrated that use of the GPS test changed initial disease management (active surveillance versus definitive treatment) for 25 percent of patients, which is consistent with previously reported studies. Sixty-three percent of the GPS-tested patient population selected active surveillance compared to 40 percent of patients from a separate group of men who did not receive the test. Of men who selected active surveillance initially, 89 percent remained on active surveillance at one year.

"With actionable information from the GPS test, urologists and patients can engage in shared decision making to better understand if active surveillance is the right option and, if it is, to move forward with confidence," said Neal D. Shore, M.D., FACS, medical director, Carolina Urologic Research Center. "These results demonstrate that the GPS test has a positive impact on reducing overtreatment of clinically low-risk prostate cancer, and improves appropriate adherence on active surveillance."

About the Oncotype DX[®] Genomic Prostate Score™ Test

Designed by Genomic

Health based on results from multiple studies led by Cleveland Clinic and the University of California, San Francisco, the Oncotype DX Genomic Prostate Score test analyzes 17 genes across four biological pathways from tumor tissue removed during biopsy to provide an individual score that, in combination with other clinical factors, further clarifies the current and future risk of the cancer prior to treatment intervention. The test enables confident treatment decisions to provide the opportunity for low- and intermediate-risk patients to avoid prostatectomy or radiation - and their side effects - while identifying men who need immediate definitive treatment. To learn more about the Oncotype DX Genomic Prostate Score test, visit www.OncotypelQ.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 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 DetectTM 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 Genomic Prostate 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 risk that test results will expand patient access and private reimbursement; 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 filed on Form 10-Q for the quarter ended March 31, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Recurrence Score, DCIS Score, Genomic Prostate Score, Oncotype DX AR-V7 Nucleus Detect and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

GHDX-P



View original content with multimedia: http://www.prnewswire.com/news-releases/new-data-reinforce-positive-impact-of-the-oncotype-dx-genomic-prostate-score-test-in-guiding-treatment-decisions-300651637.html

SOURCE Genomic Health, Inc.

News Provided by Acquire Media