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Prospective Oncotype DX® Genomic Prostate Score™ Test Data Presented at AUA and Published in Urology Establish Test's Ability to Increase Use and Persistence on Active Surveillance in Prostate Cancer Patients

Additional Oncotype DX GPS Test Study Results Represent First-ever Prospective Validation of a Tissue-based Molecular Marker in Prostate Cancer

REDWOOD CITY, Calif., May 13, 2017 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from two Oncotype DX® Genomic Prostate Score™ (GPS) test analyses based on a prospective, multi-center, 1,200-patient study. Results of one analysis, presented at the American Urological Association (AUA) 2017 Annual Meeting, prospectively validate the GPS test as an independent predictor of adverse pathology as a measure of tumor aggressiveness in men with localized prostate cancer. A second analysis, presented at AUA and published online in [Urology](#), reinforces that the GPS test significantly increases use and persistence on active surveillance.

"The Oncotype DX Genomic Prostate Score is now the only genomic test with prospective outcomes validation as a predictor of adverse pathology, in addition to being validated across all near- and long-term endpoints," said Phil Febbo, M.D., chief medical officer, Genomic Health. "The new analyses presented at AUA add to the fast-growing body of clinical evidence supporting the validity and utility of the GPS test in helping optimize the treatment of localized prostate cancer to help align care to guideline recommendations and eventually achieve better patient outcomes while decreasing healthcare spending."

Separate Analysis Published in [Urology](#) Demonstrates GPS Test Greatly Increases Both Use and Persistence on Active Surveillance

An interim analysis of the 1,200-patient study evaluated the impact the GPS test had on treatment decisions and persistence on active surveillance at one year following diagnosis. Results from 258 patients demonstrated that use of the GPS test changed initial treatment recommendations for 23 percent of patients, which is consistent with previously reported studies and highlights the value of the test in guiding initial treatment decisions. Sixty-two percent of the GPS-tested patient population selected active surveillance compared to 40 percent of the men who did not receive the test. Of men who selected active surveillance initially, the vast majority (89 percent) remained on active surveillance at one year based on personalized genomic information from the GPS test.

"With emerging clinical outcomes data, I believe we will observe a significant increase in urologists adopting state-of-the-art technologies to bring precision medicine to men newly diagnosed with prostate cancer," said Eric A. Klein, M.D., chairman, Glickman Urological and Kidney Institute, Cleveland Clinic, and principal investigator of the original Oncotype DX development studies conducted at the Cleveland Clinic. "When we see a patient who has localized cancer, genomic analysis provides information beyond traditional factors, such as Gleason score or PSA, to enable us to more accurately distinguish aggressive or life-threatening disease from indolent disease that can be effectively monitored with active surveillance. That's precision medicine in practice."

First-ever Prospective Validation Study of a Tissue-based Molecular Marker in Prostate Cancer Reconfirms GPS Test as an Accurate Predictor of Adverse Pathology

The initial findings from 122 patients across 19 centers demonstrated that the GPS result was a strong and independent predictor of adverse pathology across very low-, low- and intermediate-risk patients. Importantly, these prospective validation study results are consistent with previously published studies based on retrospective patient cohorts.

"Treatment decision-making can be emotionally difficult for prostate cancer patients and their families. By identifying patients who can choose active surveillance with confidence, we can help ensure that the majority of men diagnosed with prostate cancer will be able to avoid potentially life-altering side effects and improve their quality of life," said Lawrence Karsh, M.D., F.A.C.S., a urologist and director of the clinical research department at The Urology Center of Colorado and a principal investigator of the study. "Our study shows that the GPS test can clearly identify patients who are more appropriate for active surveillance, using state-of-the-art technology to guide treatment decisions while potentially identifying patients whose biological risk requires more immediate intervention."

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

Designed by Genomic Health based on results from multiple studies led by Cleveland Clinic, the University of California, San Francisco, and the Center for Prostate Disease Research, 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.OncotypeDX.com or www.MyProstateCancerTreatment.org.

Dr. Eric Klein is a paid consultant of Genomic Health, Inc. in providing speaker and education services for the Oncotype DX Genomic Prostate Score (GPS) test.

About Genomic Health

[Genomic Health](http://www.GenomicHealth.com), Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimize cancer care by 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 750,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ[®] Liquid Select[™] test. The company is based in [Redwood City](http://www.RedwoodCity.com), California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: [@GenomicHealth](https://twitter.com/GenomicHealth), [Facebook](https://www.facebook.com/GenomicHealth), [YouTube](https://www.youtube.com/GenomicHealth) and [LinkedIn](https://www.linkedin.com/company/genomic-health).

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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: our business model; the applicability of clinical study results to actual outcomes; the impact of results from clinical studies on market adoption of Oncotype DX tests; unanticipated costs or delays in research and development efforts; and other risks and uncertainties set forth in our filings with the Securities and Exchange Commission, including our most recent report on Form 10-Q for the quarter ended March 31, 2017. 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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