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## **Four New Studies of Oncotype DX® Genomic Prostate Score™ (GPS) Reconfirm Value of Test in Guiding Early-stage Prostate Cancer Risk Assessment and Treatment Selection**

### **Presentations at 2017 ASCO Genitourinary Cancers Symposium in Orlando, Feb. 16-18, Underscore Test's Clinical Utility in Low- and Intermediate-risk Patients**

REDWOOD CITY, Calif., Feb. 16, 2017 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) announced today the presentation of results from four studies evaluating the clinical value and utility of its Oncotype DX® Genomic Prostate Score™ (GPS) in the management of early-stage prostate cancer. Collectively, these new data highlight the test's ability to predict disease aggressiveness and refine risk stratification across National Comprehensive Cancer Network (NCCN) clinical risk groups.

"We now have 22 clinical studies, involving more than 4,200 prostate cancer patients, that distinguish Oncotype DX as the only test developed specifically for men who are deciding between active surveillance or definitive treatment. The test is validated to provide individualized information about both the current state and future risk of patients' prostate cancer," said Phil Febbo, M.D., chief medical officer, Genomic Health. "Together with the recently published economic analysis demonstrating substantial cost savings of more than \$2,200 per patient tested, the data presented will support increased adoption and reimbursement of Oncotype DX as physicians aim to bring precision medicine to their prostate cancer patients."

### **Kaiser Permanente Clinical Validation Study Confirms Oncotype DX GPS Predicts Biochemical Recurrence Across Full Spectrum of Prostate Cancer, Providing Improved Risk Stratification Beyond Clinical Risk Assessment**

A large clinical validation study, conducted in collaboration with Kaiser Permanente Northern California, has reconfirmed that the Oncotype DX GPS is a strong independent predictor of biochemical recurrence (BCR), a rise in prostate-specific antigen (PSA) in patients following surgery, which is a longer-term outcome measure of aggressive disease. To evaluate whether the GPS predicts BCR across the full spectrum of clinical risk as defined by NCCN criteria, researchers used Kaiser's database of 6,184 radical prostatectomy-treated men diagnosed with very low-, low-, intermediate- and high-risk prostate cancer. Results showed that the GPS was strongly associated with BCR both alone ( $p < 0.0001$ ) and after adjusting for PSA, clinical stage and central biopsy Gleason Score ( $p=0.002$ ). The association between the GPS and BCR was similar within different racial groups and consistent with previously published findings from the study conducted in collaboration with the Center for Prostate Disease Research in 2014.

"Biochemical recurrence following surgery identifies men for whom the surgery was not curative. Understanding a patient's individual risk for developing biochemical recurrence after treatment helps physicians and patients make well-informed treatment decisions," said Stephen Van Den Eeden, Ph.D., Kaiser Permanente Division of Research. "Our study revealed a strong association between the GPS result and biochemical recurrence that remained significant in multivariable analysis, thus demonstrating that Oncotype DX adds additional value to existing clinical criteria."

Additional data from the clinical validation study with Kaiser Permanente, including results of the analysis of the performance of the GPS in predicting the development of metastasis and prostate cancer death in patients with early-stage disease, have been accepted for presentation at future major urological meetings.

### **Prospective Study Demonstrates Oncotype DX GPS Is an Independent Predictor of High-risk Surgical Pathology (HRSP) in Men with Clinically Low-risk Disease**

In previous retrospective cohorts, the GPS was validated as a predictor of adverse pathology and BCR in prostate cancer patients treated surgically with radical prostatectomy. In this new ongoing prospective observational study, conducted in a real-world, community healthcare setting, researchers analyzed the association between the GPS and HRSP in 122 men who elected to receive radical prostatectomy for initial disease management.

Results showed that the GPS was a significant, independent predictor of HRSP ( $p=0.018$ ) across very low-, low- and intermediate-risk patients. The GPS remained significant after adjusting for NCCN risk group. These findings suggest that

the test may be valuable in treatment planning for men with clinically low-risk prostate cancer who are at risk for HRSP and may need to consider adjuvant therapy after surgery.

## **Large Study Demonstrates that Medical Conditions Common in Prostate Cancer Patients Do Not Influence the Oncotype DX GPS**

Validated molecular biomarkers can improve risk stratification in newly diagnosed patients with prostate cancer, but it is important to understand if biomarkers are influenced by common coexisting clinical conditions. Using data from the Center for Prostate Disease Research, researchers explored the association between the GPS and comorbidities - including obesity, diabetes mellitus, hypertension, hypercholesterolemia, coronary artery disease and low testosterone - in a cohort of 389 surgically treated men with clinically low-risk prostate cancer.

Results showed that there was no significant difference in GPS results between men with or without obesity, hypertension, hypercholesterolemia, diabetes mellitus or lower testosterone. These findings support the value of using the test in eligible patients, even if they have these health conditions.

## **Study of Veterans Finds Oncotype DX GPS Helps Physicians Identify Appropriate Candidates for Active Surveillance while Finding Patients with Higher-risk Prostate Cancer**

Active surveillance is a recommended management approach for low-risk prostate cancer, and studies have shown variable rates of active surveillance in the Veterans Administration (VA). This prospective study was conducted to determine treatment patterns in veterans tested with Oncotype DX and those who were not tested to help further standardize the care of early-stage prostate cancer. A retrospective medical chart review of 200 patients at six VA medical centers across the country was compared to treatments from a prospective study of 190 veterans who were offered Oncotype DX at the same centers.

Results showed that use of active surveillance was higher (74 percent) in veterans who received Oncotype DX than in veterans who did not (62 percent), with the largest increase observed in low-risk patients. The use of the test also helped improve risk stratification by identifying 24 patients who had more favorable pathology and 13 patients who had less favorable pathology than would be expected using NCCN criteria alone.

The Department of Veterans Affairs recently granted a five-year contract for Oncotype DX tests to be included in the VA Federal Supply Schedule (FSS) as part of cancer management services for patients diagnosed with early-stage breast or prostate cancer. Genomic Health will continue to work with VA hospitals to bring precision medicine to newly diagnosed cancer patients throughout the network of more than 150 centers in the United States.

### **About the Oncotype DX<sup>®</sup> Genomic Prostate Score<sup>™</sup> (GPS)**

Designed by Genomic Health based on results from multiple studies led by Cleveland Clinic and the University of California, San Francisco, the Oncotype DX GPS 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 a man's risk prior to treatment intervention. The test enables confident treatment decisions to provide the opportunity for low-risk patients to avoid prostatectomy or radiation - and their side effects - while identifying men who need immediate invasive treatment.

### **About Oncotype DX<sup>®</sup>**

The Oncotype DX<sup>®</sup> portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. The Oncotype DX Genomic Prostate Score (GPS) identifies which clinically low-risk patients are eligible for active surveillance, as well as those who may benefit from immediate treatment by predicting disease aggressiveness. With more than 700,000 patients tested in more than 90 countries, Oncotype DX testing has redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about the Oncotype DX GPS, visit [www.OncotypeDX.com](http://www.OncotypeDX.com) or [www.MyProstateCancerTreatment.org](http://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 by addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ<sup>®</sup> 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 700,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ<sup>®</sup> Liquid Select assay. The company is based in Redwood City, California, with international headquarters in Geneva,

Switzerland. For more information, please visit, [www.GenomicHealth.com](http://www.GenomicHealth.com) and follow the company on Twitter: [@GenomicHealth](#), [Facebook](#), [YouTube](#) and [LinkedIn](#).

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