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Genomic Health Presents Data Further Demonstrating Ability of Oncotype DX® Tests to Optimize Outcomes in Patients Across Cancer Types

Data from Eight Oncotype DX Studies Across Breast, Prostate and Kidney Cancers Presented at 2017 American Society of Clinical Oncology Annual Meeting

REDWOOD CITY, Calif., June 2, 2017 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced the presentation of eight studies that provide additional evidence of the value of Oncotype DX® tests in predicting clinically meaningful endpoints and outcomes across multiple cancer types. The data from patients with invasive breast, ductal carcinoma in situ (DCIS), prostate and kidney cancers were presented in oral and poster sessions at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

"As part of our mission to make precision medicine available to patients worldwide, we continue to conduct rigorous clinical validation and utility studies to ensure that our Oncotype DX tests provide reliable and actionable results," said [Phil Febbo, M.D.](#), chief medical officer, Genomic Health. "The data presented at ASCO 2017 continue to highlight the value of the Oncotype DX Breast Recurrence Score, the Oncotype DX Breast DCIS Score and the Oncotype DX Genomic Prostate Score tests in helping physicians individualize care across patient populations to improve treatment outcomes."

Large Outcomes Studies Continue to Confirm Prognostic Value of the Oncotype DX Breast Recurrence Score® Test

Multiple large prospective outcomes studies conducted by leading international study groups have previously provided evidence from real-world clinical practice in more than 63,000 invasive breast cancer patients that the Oncotype DX Breast Recurrence Score test consistently and accurately predicts the risk of distant recurrence and chemotherapy benefit. Additional analyses from three of these studies presented at ASCO 2017 continue to confirm the unique value of the Oncotype DX test:

- | An analysis of more than 49,000 patients in the Surveillance, Epidemiology, and End Results (SEER) Registry program of the National Cancer Institute (NCI) found that, in those with a Recurrence Score® (RS) < 18, reported chemotherapy use was uncommon (3-8 percent) and the five-year breast cancer-specific survival (BCSS) rate was high (> 99 percent). In the group with RS results 18-25, chemotherapy was administered more often (29 percent) and five-year BCSS was 99 percent regardless of chemotherapy use (in both the chemotherapy-treated and the non-chemotherapy-treated patients). (Abstract #537)
- | A separate analysis of the SEER Registries evaluated the relationship between the RS result and breast cancer-specific mortality (BCSM) in 6,075 patients with lobular tumors. Five-year BCSM was excellent in patients with a RS < 25 and increased with a RS > 25. In a multivariable analysis, RS results, grade, tumor size and age significantly predicted BCSM ($p < 0.001$). (Abstract #11568)

"These data show that the 21-gene Recurrence Score captures the spectrum of risk in ER-positive breast cancer," said Harold J. Burstein, M.D., Ph.D., Dana-Farber Cancer Institute and Harvard Medical School. "Additionally, the SEER experience proves that oncologists across the country can readily interpret these scores to make good treatment decisions with their patients."

- | Results of chemotherapy treatment from the prospective West German Study Group's PlanB study, one of the largest contemporary adjuvant breast cancer trials in Europe, were presented in an oral session. Findings for the group of HER2-negative, early-stage breast cancer patients with high clinical risk and RS results (> 11) showed a similar five-year disease-free survival for chemotherapy regimens with and without an anthracycline, indicating that avoiding an anthracycline may be an important option. In addition, the PlanB RS results were consistent with previous chemotherapy trials (NSABP-B28, PACS-01) showing the strong prognostic impact of the Breast Recurrence Score test in chemotherapy-treated patients. Previously presented findings from PlanB demonstrated that in women with low RS results treated with hormonal therapy alone, five-year disease-free survival was 94 percent. (Abstract #504)
- | New data show that using the Oncotype DX Breast Recurrence Score test to identify the right patients to treat with chemotherapy can benefit patients 70 years of age or older, similar to outcomes reported for younger patients. In the study, from Clalit Health Services in Israel, medical records of 458 elderly and 2,052 younger patients were examined.

Using patients' RS results, the researchers compared given treatment and subsequent outcomes. The findings showed a similar distribution of RS results between the age groups, that the RS predicted recurrence risk, and that within each RS result group (low, intermediate and high) there was no statistically significant difference in clinical outcomes between older and younger patients. (Abstract #543)

Additional Prostate Cancer Validation Studies Confirm Men with Oncotype DX Genomic Prostate Score™ Results Below 20 Should be Considered for Active Surveillance

The Oncotype DX Genomic Prostate Score (GPS) test was recently validated to predict long-term outcomes, including metastasis and prostate cancer death, in a cohort of men with clinically localized disease [in a large community-based, multi-center clinical validation study conducted at Kaiser Permanente](#).

- At ASCO, additional data confirmed that patients with a GPS result < 20 and very low-, low- or intermediate-risk prostate cancer are at very low risk of developing metastatic disease or dying from prostate cancer in the 10-year period following radical prostatectomy. Specifically, in an analysis of two large cohorts of patients with low- or intermediate-risk prostate cancer (n=828), only one man with a GPS result < 20 died of prostate cancer. (Abstract #5074)

"The latest validation of the Oncotype DX GPS test to predict the risk of prostate cancer-specific death and metastasis, in addition to adverse pathology, along with new data revealing very favorable outcomes in patients with GPS results less than 20, will assuredly enhance the ability of urologists and their low-risk patients to fully understand the patient's newly diagnosed prostate cancer. Then, through shared decision making, they will be able to better decide whether active surveillance is right for them," said Neal D. Shore, M.D., FACS, medical director, Carolina Urologic Research Center and president, LUGPA. "These results suggest that the GPS test can detect a subset of men with particularly favorable long-term prognosis who should be very good candidates for active surveillance and thus can safely avoid an interventional treatment with potential associated morbidities and costs."

- A separate study of 134 men with low- or intermediate-risk prostate cancer who were treated with radical prostatectomy showed that the GPS result was significantly associated with adverse pathology and provided prognostic information independent of and complementary to multiparametric MRI-guided biopsies. These findings suggest that the information provided by the GPS test is distinct from what may be determined from MRI, and that molecular testing may improve management selection and patient outcomes for men with localized prostate cancer, supporting confident treatment decision making. (Abstract #5063)

Oncotype DX Breast DCIS Score™ Test, Combined with Age and Tumor Size, Helps Identify Women Who Have Very Low Risk of Recurrence Following Breast-conserving Surgery Alone

A meta-analysis of data from two studies involving 773 DCIS patients who had undergone breast-conserving surgery without radiation found that the Oncotype DX Breast DCIS Score result, age, tumor size and year of surgery provided independent prognostic information on the 10-year risk of local recurrence. These findings suggest that the addition of these clinical and pathologic factors to the DCIS Score result can help physicians better determine the risk of local recurrence and guide individual decision making for DCIS patients. (Abstract #528)

Prospective Validation Study in Patients with Kidney Cancer Confirm Prognostic Value of a 16-gene Signature Developed by Genomic Health

A previously validated RT-PCR-based prognostic test for kidney cancer was applied to samples from participants in the S-TRAC trial of adjuvant sunitinib, demonstrating a strong association between the test score and radiographic progression-free survival and overall survival. In this study, the 16-gene score result predicted recurrence and survival outcomes in patients being treated as well as in those given placebo. The strongest results were observed in the placebo arm, where patients with a high score had significantly higher risk of recurrence and cancer-specific mortality, suggesting that in future studies the test may help identify patients most likely to have greatest benefit from emerging adjuvant therapies. (Abstract #4508)

About Oncotype DX®

The Oncotype DX® 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 company's flagship product, the Oncotype DX Breast Recurrence Score®, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score™ predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score™ predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention. With

more than 750,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com, www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org.

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/GenomicHealth).

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