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## **Genomic Health Presents New Data Demonstrating Value of Oncotype DX® to Optimize Breast Cancer Outcomes and Reduce Treatment Burden throughout Disease Continuum**

### **New Data Supports Expanded Use of Oncotype DX Breast Recurrence Score® Test for Predicting Treatment Benefit in Neoadjuvant Setting Large Study Demonstrates Excellent Survival without Chemotherapy in Certain Node-positive Patients with Low Recurrence Score Test Results**

REDWOOD CITY, Calif., Dec. 11, 2017 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced results of 10 studies that reinforce the unmatched value of the Oncotype DX Breast Recurrence Score® test and Oncotype DX® DCIS Score™ test in optimizing patient treatment across the breast cancer disease continuum. The data were recently presented at the 2017 San Antonio Breast Cancer Symposium (SABCS).

"Over the past 14 years, we have collaborated with clinical and academic thought leaders to present data at SABCS that has transformed breast cancer care. As this world-leading breast cancer conference marks its 40<sup>th</sup> anniversary, we are proud to contribute important new information that supports the use of Oncotype DX in both the adjuvant and neoadjuvant settings," said Steven Shak, M.D., chief scientific officer, Genomic Health. "With more than 800,000 patients served to date and outcomes data from more than 60,000 women, we have unparalleled data that facilitates a deeper understanding of the practice-changing impact of Oncotype DX testing."

#### ***Validation Shows Oncotype DX Breast Recurrence Score Test Predicts Clinical Response to Neoadjuvant Hormonal Therapy to Improve Surgical Outcomes***

Neoadjuvant systemic therapy prior to surgery, such as chemotherapy and/or hormonal therapy, can shrink tumor size and allow breast conserving surgery (BCS) in patients who may otherwise receive a full mastectomy. However, chemotherapy can be toxic and, in some patients, does not provide improved surgical outcomes over hormonal therapy. Core needle biopsy samples from 294 postmenopausal patients enrolled in the Phase 3 NEOS neoadjuvant (treatment before surgery) study of estrogen-receptor positive breast cancer and tumor size  $\geq 2$  centimeters were analyzed to determine clinical response to neoadjuvant hormonal therapy. The analysis demonstrated that Recurrence Score® (RS) results significantly predicted the likelihood of clinical response to neoadjuvant therapy ( $p < 0.001$ ). Specifically, the findings suggest that, for patients with a RS result below 18, treatment with neoadjuvant hormonal therapy alone could be an effective treatment strategy, resulting in BCS in 79 percent of cases.

"This important clinical validation study demonstrates that analyzing tumor biology with Oncotype DX in the neoadjuvant setting can help guide important treatment decisions," said Prof. Hiroji Iwata, principal study investigator, Department of Breast Oncology, Aichi Cancer Center Hospital, Nagoya, Japan. "In particular, patients with a low Recurrence Score result tend to have higher clinical response rates with neoadjuvant hormonal therapy, which makes it possible to shrink the tumor size and achieve breast conserving surgery leading to better cosmetic outcomes while limiting the impact of treatment side effects on their quality of life."

#### ***Many Node-positive Breast Cancer Patients Can Avoid Chemotherapy Based on Recurrence Score Result***

Consistent with previously published findings, an analysis from the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Registry reconfirms that breast cancer patients with node-positive disease, limited nodal involvement and RS results less than 18 have extremely low (less than 2 percent) five-year breast-cancer specific mortality (BCSM). Importantly, in patients with low RS results, five-year BCSM was low regardless of chemotherapy use. This indicates that certain node-positive patients with low RS results can forego chemotherapy and emphasizes the value of the Oncotype DX Breast Recurrence Score test in a patient population that is generally treated aggressively based on traditional clinical factors.

#### ***SEER Registry Analysis Supports New AJCC Staging Criteria, Confirming Many Patients with Poor Prognostic Factors May Be Downstaged to Stage 1A Disease Based on Their Oncotype DX Breast Recurrence Score Result***

Effective January 2018, the new American Joint Committee on Cancer (AJCC) Prognostic Stage Groups will add the Oncotype DX Breast Recurrence Score, hormonal status (ER, PR) and HER2 status to nodal status, tumor size and tumor grade for staging breast cancer. For patients with node-negative disease or micrometastases in the nodes, a low Oncotype DX Breast Recurrence Score result (RS < 11) classifies a patient as having the most favorable Prognostic Stage, regardless

of tumor grade or tumor size (up to five centimeters). In an analysis of the SEER Registry, age, tumor size and tumor grade ranged widely in patients with a RS < 11. Importantly, the 9,000 patients with a RS < 11 who were treated with hormonal therapy alone had excellent prognosis, with a five-year breast cancer-specific survival of 99.6 percent, strongly supporting the new AJCC staging criteria.

"Genomic testing has transformed the way we treat early-stage invasive breast cancer, and there is now unequivocal evidence demonstrating that Oncotype DX can consistently and accurately predict chemotherapy benefit and the risk of distant recurrence across patient populations, including those with node-positive disease," said Kevin R. Fox, M.D., director, Rena Rowan Breast Center, Penn Medicine. "By using the Recurrence Score and information based on the biology of each patient's tumor, we are able to optimally manage their disease, avoiding over- and under-treatment and ultimately reducing the burden of chemotherapy on patients and the healthcare system."

### **Additional Oncotype DX Presentations Reinforce Unmatched Value of Tests in Multiple Patient Populations**

- | Prospective 10-year, long-term clinical outcomes from a registry of more than 1,500 patients tested with Oncotype DX within Clalit Health Services, the largest health maintenance organization in Israel, demonstrated that patients with low RS results treated with hormonal therapy alone showed low 10-year distant recurrence rates. Specifically, the findings showed that use of chemotherapy was aligned with RS results, and that node-negative patients with RS results less than 18 -- the vast majority (98.2 percent) of whom were treated with hormonal therapy alone -- had excellent outcomes, with a 10-year distant recurrence risk of 4 percent.
- | A new analysis revealed distinctive biological features for breast cancer in men compared with women, and confirmed that genomic profiling with Oncotype DX testing also provides clinical value for guiding treatment decisions in men regardless of nodal status.
- | New data from the prospective West German Study Group's (WSG) PlanB study, one of the largest contemporary adjuvant breast cancer trials in Europe, reinforce the value of utilizing the Oncotype DX Breast Recurrence Score test to evaluate tumor biology in older women. The results demonstrated that patients age 70 or older, whose performance status allows them to be candidates for chemotherapy and have high Recurrence Score results, do as well as younger patients. The researchers suggest that elderly patients should receive genomic testing to determine their breast cancer risk and, if they are determined to be high risk, should receive chemotherapy to optimize outcomes.
- | Two new analyses evaluating the results from women with ductal carcinoma in situ (DCIS) confirmed the ability of the Oncotype DX DCIS Score test to provide estimates of recurrence risk.

### **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® test, 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™ test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score™ test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention. With more than 800,000 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](http://www.OncotypeIQ.com), [www.MyBreastCancerTreatment.org](http://www.MyBreastCancerTreatment.org) or [www.MyProstateCancerTreatment.org](http://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, 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 800,000 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](http://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).

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the results of clinical studies; the impact of clinical studies on reimbursement and test adoption; the applicability of clinical study results to actual outcomes; the commercial performance of the company's tests; and the benefits of the 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 risk that the company may not obtain or maintain adequate levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the ability of the company to achieve expanded coverage of reimbursement for its existing tests and the ability of any such expanded coverage to result in additional revenue; the ability of test results to change treatment decisions; the risks of competition; the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes and the ability to demonstrate sufficient clinical utility; 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 our most recent report on Form 10-Q for the quarter ended September 30, 2017. 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, Oncotype SEQ, Liquid Select, Genomic Prostate Score, GPS 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.

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