

Genomic Health Announces Positive Study Results Validating Use of Oncotype DX(R) in DCIS Breast Cancer at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium Prospectively-Designed Clinical Study Conducted by the Eastern Cooperative Oncology Group (ECOG) Demonstrates that DCIS Score Predicts Local Recurrence and Can Identify 75% of Patients with Lower-Risk Who Can Avoid Radiation Results to be Highlighted in SABCS Press Briefing on Wednesday, Dec. 7 at 7:30am CT; Complete Data Presented on Thursday, Dec. 8 at 4:30 p.m. CT Company to Make Test Available to Physicians and Their DCIS Breast Cancer Patients December 28

SAN ANTONIO, Dec. 6, 2011 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced positive results from a clinical validation study of *Oncotype DX*® in patients with DCIS (ductal carcinoma in situ of the breast) conducted by the Eastern Cooperative Oncology Group (ECOG), a clinical trials cooperative group supported by the National Cancer Institute. The study, presented at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium, met its primary endpoint by demonstrating that a pre-specified *Oncotype DX* DCIS Score goes beyond traditional clinical and pathologic measures to predict the risk of local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS in the same breast. Based on this validation, Genomic Health plans to make the *Oncotype DX* DCIS Score available to physicians and their DCIS patients on December 28, 2011.

"This is the first time a multigene test has been used to differentiate lower risk DCIS, which may be considered for treatment with surgery alone, from higher risk DCIS, for which adjuvant treatment including radiation should be considered in addition to surgery," said Lawrence J. Solin, MD, FACR, FASTRO, principal investigator for this study and Chair of the Department of Radiation Oncology at Einstein Medical Center, Philadelphia. "This study adds to the growing body of evidence showing that routine microscopic pathology grading is not a reliable indicator of the risk of recurrence."

Genomic Health researchers collaborated with ECOG to prospectively validate whether the *Oncotype DX* DCIS Score predicted 10-year local recurrence by analyzing 327 DCIS tumor specimens from patients previously enrolled in the E5194 study of breast-conserving surgery alone. The multigene DCIS Score was obtained by performing the *Oncotype DX* Breast Cancer test, using a pre-specified DCIS algorithm to predict local recurrence regardless of whether adjuvant tamoxifen was given.

The study demonstrated that 75% of patients have a low DCIS Score as pre-specified in the study and may be able to forego radiation therapy. DCIS breast cancer patients with a low DCIS Score had a low 12% likelihood of a local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS in the same breast, and an even lower 5% likelihood of developing a new invasive breast cancer. Conversely, the study demonstrated that patients with high DCIS Score had a 27% likelihood of local recurrence, of which approximately half was likely to develop a new invasive breast cancer. The DCIS Score also demonstrated consistent association with local recurrence across subgroups regardless of lesion size, grade, surgical margins, or menopausal status.

"The treatment of DCIS has been highly variable in the absence of having reliable methods to select patients for treatment with surgery alone without radiation," said Steven Shak, M.D., chief medical officer, Genomic Health. "By revealing the underlying biology of DCIS, we can now

help quantify the likelihood of local recurrence, which is key to devising an individualized treatment plan."

DCIS is an increasingly detected subgroup of breast cancer, and in the United States alone, about 45,000 patients are diagnosed with DCIS each year, accounting for approximately one out of every five new breast cancer cases. Unlike invasive breast cancer, the tumor cells in DCIS are confined to the milk ducts within the breast. Breast-conserving surgery, rather than mastectomy, has become the most common surgical procedure for patients with DCIS. After breast-conserving surgery for DCIS, local recurrences of DCIS or a new invasive breast cancer occur in 20-25% of patients at 10 years, on average, with surgery alone. The addition of radiation therapy for DCIS has been shown in clinical trials to reduce local recurrence risk, but has not been shown to prolong survival. To date, there have been no validated molecular markers that clearly differentiate low-risk from high-risk disease.

"As a two-time DCIS breast cancer survivor and patient advocate for more than 20 years, it has been frustrating to see DCIS patients being offered the same type of treatment offered to stage I invasive breast cancer patients," said Mary Lou Smith, co-founder of Research Advocacy Network. "It would have been easier for me to make a treatment decision if I would have known, with a greater degree of certainty, that I would benefit from those treatments. Now, we have the opportunity to address a critical need in the treatment of breast cancer by providing physicians and their DCIS patients with the first clinically validated genomic test to help individualize treatment decisions for this pre-invasive type of breast cancer."

The *Oncotype* DCIS Score is generated by the *Oncotype* DX Breast Cancer test, using a pre-specified DCIS Score algorithm. The E5194 study validates the DCIS Score's ability to quantify the 10-year likelihood of any local recurrence (DCIS or invasive carcinoma); and predict the 10-year likelihood of an invasive carcinoma local event based on a patient's individualized underlying tumor biology and regardless of whether adjuvant tamoxifen was given.

"The DCIS Score will help physicians understand the underlying biology of DCIS for an individual patient and accurately gauge the risk for that person, enabling the patient and physician to decide on the appropriate course of treatment based on a more complete understanding of the risk involved," said Dr. Solin.

Based on these results, Genomic Health plans to make the *Oncotype* DX DCIS Score available to physicians and their DCIS patients on December 28, 2011.

About Genomic Health and the *Oncotype* DX® Tests

Genomic Health, Inc. (NASDAQ: GHDX) is a molecular diagnostics company focused on the global development and commercialization of genomic-based clinical laboratory services that analyze the underlying biology of cancer allowing physicians and patients to make individualized treatment decisions.

Its lead product, the *Oncotype* DX Breast Cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage breast cancer to help optimize treatment options. *Oncotype* DX is the only test incorporated in published ASCO® and NCCN® breast cancer treatment guidelines for patients with node-negative breast cancer that is estrogen-receptor positive and/or progesterone-receptor positive. The test is also recognized in international guidelines issued by St. Gallen International Breast Cancer Expert Panel and European Society for Medical Oncology (ESMO).

Physicians also use the *Oncotype* DX Breast Cancer test to make treatment recommendations for certain node-positive breast cancer patients. *Oncotype* DX has been extensively evaluated in thirteen clinical studies involving more than 4,000 breast cancer patients worldwide, including a

large validation study published in *The New England Journal of Medicine* and a chemotherapy benefit study published in *the Journal of Clinical Oncology*.

The *Oncotype DX* Colon Cancer test is the first multigene expression test commercially available that has been clinically validated to predict risk of recurrence in patients with stage II colon cancer. Genomic Health collaborated with the National Surgical Adjuvant Breast and Bowel Project and Cleveland Clinic on a total of four development studies in more than 1,800 patients with stage II colon cancer. The final gene panel was then independently evaluated in more than 1,400 stage II colon cancer patients in the QUASAR validation study.

As of September 30, 2011, more than 10,000 physicians in over 60 countries had ordered more than 230,000 *Oncotype DX* tests. Genomic Health has a robust pipeline focused on developing tests to optimize the treatment of prostate and renal cell cancers, as well as additional stages of breast and colon cancers. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit

www.genomichealth.com. To learn more about *Oncotype DX* tests, visit: www.oncotypedx.com and <http://www.MyBreastCancerTreatment.org>.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our plans to launch Oncotype DX for patients with DCIS beginning on December 28, 2011; the ability of Oncotype DX testing to identify lower risk DCIS patients who may not benefit from radiation and to individualize cancer treatment for DCIS patients; the Company's belief that the presentation of the ECOG clinical validation study will enable commercialization of Oncotype DX for use in DCIS patients; the value the company's tests are delivering to physicians, payers and patients; the ability of the company to develop additional tests in the future; the scope, success or results of clinical trials and the timing of such activities; the applicability of clinical study results to actual outcomes; the ability of the company's tests to impact clinical practice and, the ability of the company's tests to be adequately reimbursed. 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 applicability of clinical study results to actual outcomes; the risks and potential delays associated with such studies; the risks and potential delays associated with the commercialization of current and future products; the risks and uncertainties associated with reimbursement of our tests or for new indications for our existing tests; the risks and uncertainties associated with the regulation of our tests; the risks associated with competition; 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 on Form 10-Q for the quarter ended September 30, 2011. 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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