Genomic Health and ECOG-ACRIN Cancer Research Group Announce Publication of Positive DCIS Validation Study in the Journal of the National Cancer Institute

Findings Demonstrate Utility of Oncotype DX® to Guide Radiation Treatment Decision for DCIS Patients and Support Expanded Access and Reimbursement

REDWOOD CITY, Calif. and PHILADELPHIA, Penn., May 2 -- Genomic Health, Inc. (Nasdaq: GHDX) and the ECOG-ACRIN Cancer Research Group announced today that the Journal of the National Cancer Institute (JNCI) published positive results from their clinical validation study of the Oncotype DX® DCIS Score in patients with ductal carcinoma in situ (DCIS), an early or pre-invasive form of breast cancer. The prospective study, designed and conducted jointly by Genomic Health and ECOG-ACRIN, established that the Oncotype DX DCIS Score goes beyond traditional clinical and pathologic measures to predict the 10-year risk of local recurrence, defined as recurrence of DCIS or invasive breast cancer in the same breast, a finding that will help to guide radiation treatment decision-making for women with DCIS who are treated by local excision. The study was published online today and is scheduled to appear in Volume 105, Issue 10 of the JNCI print edition.
"The management of DCIS has been variable in the absence of reliable methods to select patients for treatment with surgical excision alone, without radiation. The DCIS Score is a new tool that can help physicians and patients make more informed decisions," said Lawrence J. Solin, M.D., FACR, FASTRO, principal investigator for this study and chair of the Department of Radiation Oncology at Einstein Medical Center in Philadelphia, Pennsylvania.

The detection of DCIS is increasing in the United States, with more than 50,000 patients diagnosed each year. Most women with DCIS who receive breast-conserving surgery without standard radiotherapy will not develop a local recurrence, defined as either the recurrence of DCIS or the development of a new invasive cancer in the same breast. Unfortunately, traditional clinical and pathologic criteria are insufficient to define a low-risk population for whom excision alone may be adequate.

Genomic Health and ECOG-ACRIN researchers analyzed 327 DCIS tumor specimens from patients previously enrolled in the E5194 clinical trial, a prospective study of patients treated with surgical excision without radiation. E5194 was conducted by the former Eastern Cooperative Oncology Group (ECOG) and sponsored by the National Cancer Institute. The current study validated that the Oncotype DX DCIS Score predicted 10-year local recurrence (DCIS or invasive carcinoma) based on a patient's individualized underlying tumor biology regardless of whether adjuvant tamoxifen was given. At present, tamoxifen use for DCIS is variable in clinical practice.

“The development of the Oncotype DX DCIS Score is in direct response to recommendations of an expert panel convened by the National Cancer Institute in 2009 to develop and validate new tools to identify which women with DCIS may be spared radiation therapy and which are at greatest risk of developing invasive cancers that require more aggressive therapy, including chemotherapy,” said Joseph A. Sparano, M.D., therapeutic chair of the ECOG-ACRIN Breast Cancer Committee; professor of medicine (oncology) and professor of obstetrics, gynecology, and women’s health at the Albert Einstein College of Medicine; and associate chairman of the Department of Oncology at Montefiore Medical Center in Bronx, New York.

The study demonstrated that 70 percent of patients who met the eligibility criteria for participation in ECOG E5194 had a low DCIS Score and may be able to forego radiation therapy. Compared with patients whose tumor had an intermediate or high DCIS Score, patients with a low DCIS Score had a significantly lower likelihood of a local recurrence at 10 years (about 11 percent vs. 26 percent, respectively). In addition, a low DCIS Score was associated with a significantly lower risk of developing invasive breast cancer, which was approximately 4 percent in the low score group, 12 percent in the intermediate score group, and 19 percent in the high score group. The DCIS Score was predictive of local recurrence across patient subgroups regardless of lesion size, grade, surgical margins, or menopausal status.
“This publication adds to the growing body of evidence showing that microscopic pathology grading alone is not a reliable indicator of the risk of recurrence and the need for more intensive treatment,” said Steven Shak, M.D., chief medical officer and executive vice president of research and development at Genomic Health. “Together with the recently presented positive cost effectiveness data in DCIS, we believe these peer-reviewed published results pave the way to expand reimbursement and increase patient access to the Oncotype DX DCIS Score.”

In addition to the Oncotype DX DCIS Score, Genomic Health provides the Oncotype DX Recurrence Score for patients with early-stage invasive breast cancer and is the only clinically validated genomic test predictive of chemotherapy benefit and incorporated in major cancer treatment guidelines.

About the ECOG-ACRIN Cancer Research Group

The ECOG-ACRIN Cancer Research Group, a member network that designs and conducts biomarker-driven cancer research involving adults who have, or are at risk of developing, cancer, was formed in May 2012 by the merger of the Eastern Cooperative Oncology Group (ECOG) and the American College of Radiology Imaging Network (ACRIN), two highly respected National Cancer Institute (NCI)-sponsored cancer cooperative groups. The Group comprises nearly 650 member institutions, including community hospitals; academic medical centers; NCI-designated cancer centers, Community Cancer Oncology Programs (CCOPs) and Minority-based CCOPs, health systems, and physician practices, in the United States and around the world. Approximately 6000 individual physicians, translational scientists, and associated research professionals from the member institutions are involved in Group research, which is organized into three programs: Biomarker Sciences, Therapeutic Studies, and Cancer Control and Outcomes. For more information, visit www.ecog-acrin.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is a global healthcare company that provides actionable genomic information to personalize cancer treatment decisions. The company's lead product, the Oncotype DX® breast cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer and has been shown to predict the likelihood of recurrence in ductal carcinoma in situ (DCIS). In addition to this widely adopted test, Genomic Health provides the Oncotype DX colon cancer test, the first multi-gene expression test developed for the assessment of risk of recurrence in patients with stage II and stage III disease. As of March 31, 2012, more than 19,000 physicians in over 70 countries had ordered more than 350,000 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 treatment decisions in breast and colon cancers. The company is based in Redwood

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the ability of the company's Oncotype DX test to predict loco regional recurrence in node positive breast cancer patients and the potential ability of the test to be used in radiation treatment decisions; the applicability of clinical study results to actual outcomes; the ability of the test to impact clinical practice; the expectations for and timing of reimbursement for the Oncotype DX in DCIS patients; the attributes and focus of the company's product pipeline; the potential economic benefits associated with the company's tests; and the demand for the company's tests. 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 results of clinical studies; the applicability of clinical study results to actual outcomes; the risks and potential delays associated with such studies; the risks and uncertainties associated with coverage and reimbursement; the risks and uncertainties associated with possible additional regulation of the company’s tests both in the United States and abroad; the risks associated with competition; 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 the risks set forth in the company's Annual Report on Form 10-K for the quarter ended December 31, 2012. 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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