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## **Genomic Health Announces New Evidence Further Demonstrating Clinical Utility and Cost-Effectiveness of Oncotype DX in Colon Cancer**

### **Data Presented at the 2013 Gastrointestinal Cancers Symposium Show Test Significantly Changes Treatment Decisions, May Reduce Medical Costs While Increasing Patient Well-Being Journal of Clinical Oncology Accepts for Publication Second Successful Validation Study Confirming Oncotype DX Colon Cancer Test Provides Value Beyond Conventional Markers**

REDWOOD CITY, Calif., Jan. 23, 2013 /PRNewswire/ -- [Genomic Health](#), Inc. (Nasdaq: GHDX) today announced results from three studies of the [Oncotype DX](#)<sup>®</sup> Colon Cancer test at the 2013 Gastrointestinal (GI) Cancers Symposium, including new data demonstrating that Recurrence Score<sup>®</sup> (RS) results changed treatment recommendations in 45 percent of the enrolled stage II colon cancer patients. Presentations also include positive findings from a second health economics analysis suggesting that use of the test may result in a significant reduction in direct medical costs and improve patient well-being.

Additionally, the company announced that the *Journal of Clinical Oncology* (JCO) has accepted for publication results from its second large clinical validation study of stage II colon cancer patients enrolled in CALGB 9581 confirming that the Oncotype DX test improves the ability to differentiate higher from lower recurrence risk beyond conventional factors.

"These new data reinforce the value of an individualized recurrence risk assessment score that enables physicians to identify those at high risk of recurrence who can experience a greater potential benefit from chemotherapy, as well as patients with a low risk of recurrence who can be spared unnecessary treatment," said [Steven Shak, M.D.](#), chief medical officer and executive vice president for research and development at Genomic Health. "Oncotype DX represents an important advance in bringing personalized medicine into the modern paradigm for cancer care. With a growing body of evidence, and a second publication in JCO, we now have expanded support for broader reimbursement and increased patient access to our colon cancer test."

#### **Oncotype DX Colon Cancer Test Changes 45 Percent of Treatment Decisions**

"Current clinical practice reveals a high level of variability and subjectivity in the treatment of stage II colon cancer patients," said Steven Alberts, M.D., medical director for the Clinical Research Office in the Mayo Clinic Cancer Center, Rochester, Minn. "The Oncotype DX Colon Cancer test changes the paradigm for predicting individual recurrence risk for stage II colon cancer patients by providing quantitative information which has not been available with conventional measures."

- Conducted in collaboration with the Mayo Clinic Cancer Research Consortium, a prospectively designed study analyzed treatment decisions for 141 stage II, T3 MMR-proficient colon cancer patients across 17 sites demonstrating that the use of the Oncotype DX Colon Cancer test changed treatment decisions 45 percent of the time and led to an overall reduction in chemotherapy use.

For patients whose treatment recommendations changed, treatment intensity decreased for more than 33 percent of patients (from chemotherapy to observation or from oxaliplatin-containing to non-oxaliplatin containing regimens) and increased for more than 11 percent of patients (from observation to any chemotherapy or from non-oxaliplatin containing to oxaliplatin-containing treatment).

Abstract #453: "Prospective evaluation of a 12-gene assay on treatment recommendations in stage II colon cancer patients" will be presented on Saturday, January 26, from 7:00—7:55 a.m. Pacific Time at Moscone West, San Francisco, Calif.

#### **Second Health Economics Study Reconfirms Test's Cost Effectiveness**

- An analysis of 141 patients from 17 sites in the Mayo Clinic Cancer Research Consortium demonstrated the value of using the Oncotype DX test to identify stage II colon cancer patients with low risk of recurrence. After receiving the Recurrence Score results, physician recommendations for adjuvant chemotherapy in patients with low risk of recurrence decreased by 22 percent, which resulted in direct medical care costs savings of \$4,200 per patient.

This is the first health economic study of the Oncotype DX Colon Cancer test conducted in clinical practice. A separate modeling study showing that the use of the Oncotype DX test in stage II colon cancer patients may lead to health care cost savings while improving clinical outcomes was recently published in the December 2012 issue of *Value of Health*.

Abstract #391: "Real-world comparative economics of a 12-gene assay for prognosis in stage II colon cancer" will be presented on Saturday, January 26, from 7:00—7:55 a.m. Pacific Time at Moscone West, San Francisco, Calif.

Additionally, a poster titled: "Impact of the Recurrence Score (RS) result and mismatch repair status (MMR) on agreement between oncologists (MDs) for stage II colon cancer (CC) recurrence risk (RR) assessment: A novel clinical utility endpoint for prognostic markers" (Abstract #349) will be presented on Saturday, January 26, from 7:00 - 7:55 a.m. Pacific Time at Moscone West, San Francisco, Calif.

Four leading medical specialty societies co-sponsor the three-day, multidisciplinary symposium, including the American Gastroenterological Association Institute, the American Society of Clinical Oncology, the American Society for Radiation Oncology and the Society of Surgical Oncology (SSO).

### **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<sup>®</sup> 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 September 30, 2012, more than 10,000 physicians in over 65 countries had ordered more than 320,000 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 City](#), California with European headquarters in Geneva, Switzerland. For more information, please visit, [www.GenomicHealth.com](http://www.GenomicHealth.com). To learn more about the [Oncotype DX tests](#), visit: [www.OncotypeDX.com](http://www.OncotypeDX.com) and [www.mybreastcancertreatment.org](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 the ability of the company's colon cancer test to impact treatment decisions in a clinical setting; the ability of test to reduce the use of chemotherapy and the direct medical costs associated with treating colon cancer; the potential of the company's test to change medical practice in the treatment of stage II or stage III colon cancer; the ability of the company to secure additional reimbursement for its colon cancer test; the applicability of study results to clinical practice; the timing and results of future studies or clinical trials; the focus and attributes of the company's product pipeline; the ability of the company to develop additional tests in the future; and the ability of any potential tests the company may develop to optimize cancer treatment. 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 uncertainties associated with possible additional regulation of the company's tests both in the United States and abroad; the availability and extent of reimbursement coverage; risks associated with the commercialization of current and future tests; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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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