



## **Genomic Health Presents Six New Studies Including Four Oral Presentations in Breast, Colon and Renal Cancers at American Society of Clinical Oncology (ASCO) Annual Meeting**

### **Continued Research on Commercialized Products and Pipeline Reflects Company's Ongoing Commitment to Develop and Deliver Genomic Tools to Individualize Cancer Treatment Decisions**

CHICAGO, June 5, 2010 /PRNewswire via COMTEX News Network/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced the results of six studies being presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, including an evaluation of biological similarities and differences between stage II and III colon cancer, suggesting a potential role for the Onco<sup>type</sup> DX(R) colon cancer test in patients with stage III disease, pending further study. The company also announced the first presentation of results from its collaboration with Pfizer Oncology for assessing prognosis for early-stage renal cell carcinoma.

"With our innovative clinical collaborations and access to numerous landmark trials, we have the opportunity to advance the quality of cancer treatment decisions as evidenced by the six studies being presented at ASCO," said Steven Shak, M.D., chief medical officer of Genomic Health. "Collectively these results reflect our efforts to continue adding value to the Onco<sup>type</sup> DX breast and colon cancer tests, while advancing our broad and deep product pipeline aimed at optimizing treatment decisions in multiple tumor types."

#### ***Potential Role for Onco<sup>type</sup> DX Colon Cancer Test in Stage III Disease***

An evaluation of biological similarities and differences between stage II and III colon cancer suggests that the Onco<sup>type</sup> DX colon cancer Recurrence Score(R), currently available for treatment planning in stage II colon cancer, may also predict recurrence risk in stage III colon cancer. The study, "Comparison of molecular and pathologic features of stage II and stage III colon cancer in 4 large studies conducted for development of the 12-gene colon cancer Recurrence Score" (Abstract #3503), will be presented in an oral discussion on Sunday, June 6.

"Some tumor characteristics, such as grade, and a small number of individual genes were identified that may distinguish stage II and III colon cancers. However, there is a striking similarity between the two stages for the vast majority of the 375 genes studied and for the 12-gene Onco<sup>type</sup> DX colon cancer Recurrence Score," said Michael J. O'Connell, M.D., associate chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP). "Earlier this year physicians began incorporating Onco<sup>type</sup> DX into clinical practice for stage II colon cancer patients. We are now conducting additional research to evaluate this test for treatment planning in stage III disease, based on the similarities observed in this study."

Pathologic markers and expression of 375 genes were compared between 634 stage II and 844 stage III patients across four studies that were conducted to develop the Onco<sup>type</sup> DX colon cancer test. Results demonstrated that the vast majority of the 375 genes and the Recurrence Score appeared to be stage-independent, both in terms of the levels of gene expression and the relationships to patient outcome. However, there were differences identified between stage II and stage III colon cancer for some tumor characteristics and a small number of the individual genes which warrant further study. The investigators concluded that the clinical relevance of these differences between stage II and III colon cancer should be further examined in prospectively designed studies.

#### ***Leveraging Access to Large Studies to Refine Understanding of Breast Cancer Biology, Recurrence***

The racial disparity in breast cancer has been well-documented in community practice as well as clinical trials; however causes of the differences in incidence, mortality, and age of disease onset between women of African ancestry and women of other racial and ethnic backgrounds are not yet fully understood. Using the Onco<sup>type</sup> DX breast cancer Recurrence Score in an analysis of the SWOG 8814 adjuvant breast cancer clinical trial previously conducted by the Southwest Oncology Group (SWOG), researchers identified higher levels of proliferation genes in 27 African American ER-positive breast cancer patients compared to 340 other patients as a potential biologic cause of racial survival disparity observed in this study.

"This analysis suggests worse survival among African-American breast cancer patients was due in large part to tumors with higher proliferation and not to differences in degree of endocrine responsiveness," said Kathy S. Albain M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Loyola University Chicago Stritch School of Medicine, Cardinal Bernardin Cancer Center, Loyola University Health System, Maywood, IL, and first author of the study. "These intriguing findings provide a starting point for additional research, which may impact adjuvant treatment selection for this patient

population."

The study, "Potential biologic causes of the racial survival disparity in adjuvant trials of ER-positive breast cancer" (Abstract #511), examined estrogen receptor-positive patients with node positive disease and found that even after adjusting for treatment and other prognostic factors, African-American patients still had a 44 percent higher risk of death than the rest of the patient population. Gene expression analysis with *Oncotype DX* found significantly higher levels of expression of four genes related to proliferation in African-American patients ( $p < 0.05$ ).

Additionally, Genomic Health, in partnership with investigators from several academic institutions, will present a separate study, "Recurrence risk of node-negative and ER-positive early stage breast cancer patients by combining Recurrence Score, pathologic, and clinical information: A meta analysis approach" (Abstract #509), demonstrating that combining the *Oncotype DX* Recurrence Score with pathology and clinical measures (RSPC) supplements the assessment of baseline recurrence risk. The *Oncotype DX* Recurrence Score (RS), and the individual biology it identifies, remains the recommended method for predicting relative chemotherapy benefit for early-stage breast cancer.

Physicians currently integrate the RS result with other pathology and clinical (PC) measures through their own individual processes and have not had a formal way of integrating this information when assessing recurrence risk. Using this meta-analysis approach, Genomic Health and its clinical collaborators have employed statistical methods to leverage the larger experience of over 1,700 breast cancer patients from two randomized trials, and integrate the RS with PC measures in order to provide greater clarity, especially when PC measures and the RS are discordant.

The RSPC prediction of recurrence risk, which is driven in large part by the RS, reflects the individualized assessment of the continuous biology of breast cancer. For the majority of patients, the prediction of recurrence risk by RSPC and RS are similar. As expected, changes in risk category occurred more frequently for scores near the category boundaries and were most likely for patients with intermediate Recurrence Scores. The integration of all these measures reduced the number of patients classified as intermediate risk by 30 percent. Genomic Health and its clinical collaborators are working to make this statistical tool available online.

Both of these studies will be presented in oral discussions on Monday, June 7.

### ***Largest Genomic Analysis of Localized Clear Cell Renal Carcinoma***

Yesterday, Genomic Health announced the first publicly presented results from its collaboration with Pfizer Oncology to study early-stage renal cell carcinoma prognosis, which demonstrated a strong correlation between gene expression and recurrence risk in this patient population. The study, "Identification of Prognostic Genomic Markers in Patients with Localized Clear Cell Renal Cell Carcinoma" (Abstract 4501), is the largest genomic analysis of localized clear cell renal carcinoma performed to date. It will be presented in an oral discussion on Saturday, June 5.

### ***Other Breast Cancer Studies***

- Researchers in Israel, where *Oncotype DX* is standard of care in both node negative and node positive breast cancer, evaluated the correlation between the *Oncotype DX* Recurrence Score and use of adjuvant chemotherapy in 260 node-positive breast cancer patients. Results demonstrate that the Recurrence Score and number of positive nodes influenced treatment decisions in these breast cancer patients, with the use of chemotherapy increasing as the RS increased. The study, "The Recurrence Score and chemotherapy treatment in node-positive, ER+ early-stage breast cancer patients in Israel" (Abstract 6075), will be presented in a poster on Monday, June 7.
- In the study, "Association of vorinostat with decrease in gene expression of proliferation-related genes in tumors from women with newly diagnosed breast cancer" (Abstract 3097), researchers evaluated biomarker modulation in breast cancer tissues obtained from newly-diagnosed invasive breast cancer patients who received vorinostat, a chemotherapy agent. Results indicated short-term use vorinostat was associated with decreases in expression of proliferation-associated genes, and researchers plan to design future studies combining vorinostat with other therapies. This study will be presented in a poster on Monday, June 7.

### **About *Oncotype DX*(R) Breast Cancer Test**

The *Oncotype DX* breast cancer test is the first and only multigene expression test to be recommended by both the American Society of Clinical Oncology and the National Comprehensive Cancer Network, to predict the likelihood of chemotherapy benefit as well as recurrence, for patients with node-negative breast cancer that is estrogen-receptor positive and/or progesterone-receptor positive. Additionally, physicians use *Oncotype DX* to make treatment recommendations for certain node-positive breast cancer patients, and the test report also provides quantitative scores for select individual genes. *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*. Both Medicare and private health plans covering over 90 percent of U.S. insured lives provided reimbursement for *Oncotype DX* for patients with node-negative breast cancer that is estrogen-receptor positive and/or

progesterone-receptor positive through contracts, agreements or policy decisions. For more information about Oncotype DX for breast cancer, please visit [www.oncotypedx.com](http://www.oncotypedx.com).

### **About Oncotype DX(R) Colon Cancer Test**

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. For its colon cancer program, Genomic Health and its collaborators used the same rigorous clinical development strategy and standardized quantitative technology designed for the company's Oncotype DX breast cancer test. National Surgical Adjuvant Breast and Bowel Project (NSABP) conducted three development studies and Cleveland Clinic conducted one development study, all of which were funded by Genomic Health, analyzing 761 genes from 1,851 patients with stage II colon cancer. The final set of seven recurrence and five reference genes were then independently evaluated in 1,436 stage II colon cancer patients in the QUASAR validation study. Availability of the test in New York is pending review by the state, as is required for all laboratory developed tests. For more information about Oncotype DX for colon cancer, please visit [www.oncotypedx.com](http://www.oncotypedx.com).

### **About Genomic Health**

Genomic Health, Inc. (NASDAQ: GHDX) is a life science company focused on the global development and commercialization of genomic-based clinical laboratory services for cancer that allow physicians and patients to make individualized treatment decisions. In 2004, Genomic Health launched the Oncotype DX(R) breast cancer test, which has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in early-stage breast cancer. In addition to the widely adopted Oncotype DX breast cancer test, Genomic Health launched its Oncotype DX colon cancer test in January 2010. As of March 31, 2010, more than 10,000 physicians in over 55 countries had ordered more than 148,000 Oncotype DX tests. The company was founded in 2000 and is located in Redwood City, California. For more information, please visit [www.genomichealth.com](http://www.genomichealth.com).

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the belief that the company's colon cancer test may predict recurrence risk in stage III colon cancer; the company's belief that it has the opportunity to advance the quality of cancer treatment decisions; the company's ability to continue adding value to its tests while advancing its product pipeline ;the company's belief that its research and pipeline reflect its ongoing commitment to develop and deliver tools to individualize cancer treatment decisions; the belief that study data may warrant or result in additional clinical studies or impact treatment decisions; the continuation and success of our collaboration with Pfizer Oncology; and the applicability of clinical study results to actual outcomes. 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 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; the risks and uncertainties associated with developing new tests or technologies; continued access to tissue samples; 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 March 31, 2010. 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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