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Genomic Health, Inc. and Istituto Nazionale Tumori Announce Encouraging Preliminary Clinical Trial Results of Onco*type* DX™ Assay in Predicting Response to Chemotherapy in Breast Cancer

-- Genomic Health nears expanded clinical collaborations in EGFR response --

NEW ORLEANS – June 5, 2004 – Genomic Health, Inc. and Istituto Nazionale Tumori, a leading cancer research institute located in Milan, Italy, today announced preliminary results of a clinical trial in which the patterns of expression of a substantial number of genes were clinically correlated to a pathologic complete response to chemotherapy. The study also showed that the Oncotype DX Breast Cancer Assay Recurrence Score significantly correlated with response to chemotherapy in breast cancer patients. These results were presented today at the annual meeting of the American Society of Clinical Oncology (ASCO).

"We are encouraged by these early findings," said Luca Gianni, M.D., Istituto Nazionale Tumori. "Of the 383 genes analyzed, 86 correlated with pathologic complete response, or absence of visible tumor, an effect of chemotherapy that predicts for long-term efficacy. Out of those genes, we defined scores strongly associated with response to chemotherapy, and we now plan to validate them in different patients and different studies," said Dr. Gianni. "Notably, patients in our study who were categorized as high risk by a previously validated assay," continued Dr. Gianni referring to the Oncotype DX

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assay “were more likely to respond to chemotherapy, and those categorized as lower risk were less likely to respond to chemotherapy, a result that biologically and pharmacologically makes sense.”

“These findings show that our 21-gene Oncotype DX Recurrence Score not only quantifies the likelihood of breast cancer recurrence but may also provide information on the response to chemotherapy,” said Steven Shak, M.D., chief medical officer, Genomic Health. “These and other preliminary study results will form the basis for a unique gene panel aimed at response to chemotherapy that we plan to validate in a large-scale trial estimated to begin by the end of 2004,” said Dr. Shak.

Genomic Health and the Istituto Nazionale Tumori performed RNA analysis of 383 genes in stored, paraffin-embedded tumor biopsies from 89 patients with locally advanced breast cancer treated with doxorubicin and paclitaxel to determine whether these genes were predictive in cases in which chemotherapy caused the cancer to disappear, known as a pathologic complete response. A significant correlation was observed in 86 genes ($p<0.05$), including genes related to the estrogen receptor system, proliferation and the immune system. In addition, a pathologic complete response was more likely with high Recurrence Scores and less likely with low Recurrence Scores as determined by the Oncotype DX 21-gene panel currently sold by Genomic Health ($p=0.005$).

“Over the last two years we have asked for and received valuable advice from clinical collaborators and breast cancer advocates on the development of Oncotype DX and, based on that input, Genomic Health has expanded its program of breast cancer studies,” said Randy Scott, Ph.D., chairman and CEO, Genomic Health. “Genomic Health has extended its focus from recurrence of breast cancer to response to chemotherapy. Oncotype DX has the ability to reset our thinking on the classification of patients with high and low risk by using quantitative molecular pathology to improve on current diagnosis of breast cancer. We believe that a significant number of breast cancer patients

can be better classified using this new genomic approach resulting from a better scientific understanding of tumors that are more likely to recur and tumors that are more likely to respond to chemotherapy," said Dr. Scott.

Genomic Health has clinically validated technology to analyze RNA from fixed paraffin-embedded tissues (FPET), which are routinely collected and stored for virtually all tumor tissue samples worldwide. The National Surgical Adjuvant Breast and Bowel Project (NSABP) reported in December of 2003 a large-scale validation study demonstrating that Genomic Health's Oncotype DX assay accurately quantifies the likelihood of breast cancer recurrence in node-negative, ER-positive and tamoxifen-treated patients. The study also showed that the Recurrence Score determined by the assay provides a level of correlation to breast cancer recurrence and performance that exceeds standard measures, such as patient age, tumor size and tumor grade. Oncotype DX was made available to physicians and patients in January 2004.

ASCO's "Best of Oncology" to Feature NSABP Validation Study of Oncotype DX

The NSABP/Genomic Health validation study, entitled, "Multi-gene RT-PCR assay for predicting recurrence in node negative breast cancer patients – NSABP studies B-20 and B-14," was selected from numerous studies by the ASCO Cancer Education Committee to be presented in a special session called "Best of Oncology/Society Abstracts" on Tuesday, June 8 at 9:15-10:45am (CDT). This study was originally presented at the San Antonio Breast Cancer Symposium in December 2003.

Economic Analysis of Oncotype DX

There will be a poster presentation (Abstract # 6036, Poster #28) today at 2:00pm (CDT) of an economic analysis of the results of the NSABP validation study of Oncotype DX entitled "Economic analysis of targeting chemotherapy (CT) using a 21 gene RT-PCR assay in lymph node negative (LN-), estrogen receptor positive (ER+) early-stage breast cancer (ESBC)."

Genomic Health Clinical Program to Include Response to New EGFR Therapies

Genomic Health has completed two preliminary clinical studies that have resulted in patent filings with regard to gene expression as a predictor of response to the EGFR inhibitor class of drugs. As a result of these studies, Genomic Health is currently in discussions with various clinical collaborators and expects to begin expanded studies in the near future looking at genomic markers that will predict response to these drugs. The company is developing a solid pipeline of products and services in the areas of recurrence and response to chemotherapy and response to targeted treatments that it believes will produce a steady stream of commercial assays for a variety of cancers all aimed at revolutionizing cancer care by improving treatment decisions based on the molecular signature of tumors

Genomic Health Financial Update

Genomic Health is in strong financial condition having recently raised $30 million through a Series E financing completed in April 2004, which brings the total capital investment in the company to more than $80 million. Genomic Health added Integral Capital Partners, JP Morgan-Fleming, Invesco, CS First Boston, and a major pharmaceutical company, Pfizer Inc, to its original leading group of investors, which include Kleiner Perkins Caufield & Byers, Versant Ventures, Baker/Tisch, Texas Pacific Group and JP Morgan. In addition, Parag Saxena from Invesco has joined the company's Board of Directors.

Genomic Health, Inc. is a health care services company that employs sophisticated genomic research to develop clinically validated molecular diagnostics. Genomic Health's goal is to provide individualized information on the likelihood of disease recurrence and response to therapy in order to improve the quality of treatment decisions for patients with cancer. The company was founded in August 2000 and is located in Redwood City, California.

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