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**The National Surgical Adjuvant Breast and Bowel Project (NSABP) and Genomic Health, Inc. Announce Positive Results from Large-Scale, Prospective Validation Study to Quantify Breast Cancer Recurrence in Newly Diagnosed Patients**

*-- First Large-Scale, Multi-Center Validation of a Genomic Assay from Fixed Paraffin-Embedded Tissue; Performance Exceeded Standard Measures of Patient Age, Tumor Size and Tumor Grade in Quantifying Recurrence --*

**SAN ANTONIO – December 4, 2003** – The National Surgical Adjuvant Breast and Bowel Project (NSABP) and Genomic Health, Inc. today announced that their large, prospective trial met its defined endpoints and validated that Genomic Health’s unique breast cancer assay can accurately and precisely quantify the likelihood of breast cancer recurrence in a large segment of newly diagnosed breast cancer 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. These results, which were presented at the 26<sup>th</sup> Annual San Antonio Breast Cancer Symposium, are the first large-scale, multi-center validation of a multi-gene assay. It is also the first time that such a study has been

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conducted using thin sections from standard diagnostic pathology specimens (fixed paraffin-embedded tissue) that are routinely available.

“We are excited about the results of this trial, which represent a practical advance in breast cancer diagnosis because the assay uses tumor tissue that is routinely obtained and stored for every patient,” said Norman Wolmark, M.D., chair of the National Surgical Adjuvant Breast and Bowel Project (NSABP), and the Department of Human Oncology at Allegheny General Hospital in Pittsburgh, Pennsylvania. “Based on our studies, the recurrence score becomes as important a prognostic measure for this group of node-negative patients as nodal status is for all patients,” said Dr. Wolmark.

Using NSABP’s extensive patient database, NSABP and Genomic Health designed a blinded, prospective validation using surgical tissue samples from 668 patients, who were node-negative, ER-positive and tamoxifen-treated. These tissue samples were from patients who enrolled in the NSABP B-14 clinical trial from 1982-1988 and whose outcomes have been tracked over time by NSABP sites. Using RNA analysis of tumor tissues, the study evaluated Genomic Health’s breast cancer assay to determine the likelihood of breast cancer recurrence as defined by a recurrence score from 0-100. The recurrence score was able to accurately assign patients into high and low risk groups ( $p < 0.00001$ ), and when the recurrence score was examined together with age and tumor size in a multivariate analysis only recurrence score remained a significant predictor of patient outcome ( $p < 0.00001$ ).

“The results of this trial demonstrate a major advance in molecular pathology by showing that the performance of this genomic assay exceeds the standard measures of patient age, tumor size and tumor grade, characteristics that clinicians have used to predict prognosis for the better part of a century,” said Soonmyung Paik, M.D., director, Division of Pathology, NSABP. “Even more important is the fact that we can perform this assay in a

reproducible and accurate manner using routinely available diagnostic biopsy tissue, unlike other genome based assays which require special handling, such as snap freezing in liquid nitrogen. We believe our findings will provide critical information for this substantial group of patients,” said Dr. Paik.

The NSABP trial studied a specific population of breast cancer patients, those who were node-negative, hormone-receptor-positive and tamoxifen-treated. This is a substantial breast cancer patient population, making up approximately 70 percent of the newly diagnosed node-negative patients each year.

Genomic Health’s breast cancer assay used in the NSABP trial is the first gene panel to be validated in a large-scale, multi-center, prospective validation study. The study showed that using multiple genes is more powerful than using single genes and will provide more consistent and reliable information for physicians and patients. The gene panel includes genes related to the estrogen receptor, HER2, proliferation and invasion as well as several other important categories.

“These validated, pivotal findings provide physicians and patients with quantifiable information that we believe will greatly improve treatment planning,” said Steven Shak, M.D., chief medical officer of Genomic Health, Inc. Genomic Health plans to make its assay available in early 2004 as a clinical laboratory service under the name *OncotypeDX*<sup>TM</sup>.

“The results of our trial with NSABP mark the beginning of a new era in individualized medicine by demonstrating for the first time the practical application of genomic research to the development of validated molecular diagnostics in the treatment of cancer,” said Randy Scott, Ph.D., chairman and CEO of Genomic Health, Inc. and co-founder of Incyte, the world’s first genomic information business. Genomic Health has already begun to expand the study of the *OncotypeDX* service in other cancer patient populations

related to disease recurrence and is also studying the responsiveness of individual tumors to chemotherapy and specific targeted therapies.

The NSABP is a not-for-profit, clinical trials cooperative group, which includes a network of over 300 professionals located in the U.S., Canada and Puerto Rico. Research conducted by the NSABP is supported primarily by grants from the NCI. For more than 40 years, the NSABP has successfully conducted large-scale, randomized clinical trials in colorectal and breast cancer that have altered and improved the standard of care for men and women with these diseases. To learn more about the NSABP, please visit our Web site at <http://www.nsabp.pitt.edu>.

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. Genomic Health has the financial backing of some of the world's leading capital and financial institutions, including Kleiner Perkins Caufield & Byers, JP Morgan, Versant Ventures, Texas Pacific Group and Baker/Tisch. The company was founded in August 2000 and is located in Redwood City, California.

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