Contacts:
Kathleen Rinehart/GHI: 408/460-9116
Jim Weiss/GHI: 415/609-3680
Lori Garvey/NSABP: 412/330-4621

The National Surgical Adjuvant Breast and Bowel Project (NSABP) and Genomic Health, Inc. Announce Positive Study Results Demonstrating Oncotype DX Genomic Breast Cancer Assay Predicts Chemotherapy Response

*-- **New England Journal of Medicine** Publishes NSABP Validation Study of Oncotype DX that Quantifies Likelihood of Recurrence in Early Stage Breast Cancer Patients --*

-- Kaiser Permanente Presents Results from Large Community-Based Study Consistent with NSABP Recurrence Study Findings –

-- Live Teleconference to discuss these findings at San Antonio Breast Cancer Symposium--

SAN ANTONIO, TX – December 10, 2004 – The National Surgical Adjuvant Breast and Bowel Project (NSABP) and Genomic Health, Inc. today announced positive results of a new study demonstrating that the Oncotype DX™ 21-gene panel that quantifies the likelihood of breast cancer recurrence for a large portion of early stage breast cancer patients also predicts the magnitude of chemotherapy benefit in these patients. These findings challenge the common assumption that all women benefit similarly from chemotherapy. The new study results were presented today at the 27th Annual San Antonio Breast Cancer Symposium (SABCS) and coincide with the *New England Journal of Medicine* publication of the NSABP validation study demonstrating that Oncotype DX quantifies the likelihood of recurrence in node-negative, estrogen receptor-positive breast cancer.

-- more --

"Our study discloses that the same 21-gene panel that we demonstrated could quantify breast cancer recurrence, can also predict response to chemotherapy," 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. "These data advance the state of the art in cancer care and call for a reevaluation of treatment practice. By using the Oncotype DX assay, physicians can more effectively optimize a treatment plan and avoid under treating and over treating breast cancer patients," said Dr. Wolmark.

The NSABP B-20 chemotherapy benefit study of 651 patients demonstrated that breast cancer patients with high Recurrence Scores (and high risk of recurrence), as identified by the Oncotype DX assay, also have a large absolute benefit from chemotherapy. This group represents about 25 percent of patients with node-negative, estrogen receptor-positive breast cancer. Patients with low Recurrence Scores (and low risk of recurrence) only derive minimal if any benefit from chemotherapy and represent about 50 percent of these patients.

"These studies represent a major advance in our understanding of the role of molecular profiling in breast cancer treatment, work that is critical in our national efforts to fight cancer," said Dr. JoAnne Zujewski, head, Breast Cancer Therapeutics, Clinical Investigations Branch, National Cancer Institute (NCI). "The development of this test reflects the cooperative efforts of breast cancer research groups, patient advocacy, industry, and the federal cancer research program. NCI's longstanding support of the clinical trial process and tumor tissue banks took years off the process needed to gather data to validate the test."

***New England Journal of Medicine* Publishes NSABP Validation Study**

The NSABP and Genomic Health also announced today that the *New England Journal of Medicine* published the results of their large-scale, validation trial demonstrating that the Oncotype DX 21-gene assay quantifies the likelihood of breast cancer recurrence in a large portion of early stage patients.

The *Journal* is publishing the study today online as an "early release" to coincide with the NSABP data presentations at SABCS. The same study will appear in the December 30 print edition.

The study showed that the "Recurrence Score" determined by Oncotype DX provides a level of correlation to breast cancer recurrence that exceeds standard measures, such as patient age, tumor size and tumor grade. Importantly, the results indicate that approximately 50 percent of patients are reclassified (from low risk to higher risk, or from higher risk to low risk) by the Recurrence Score when compared to classification by existing guidelines based on the standard measures. These data, originally presented at the 26th Annual San Antonio Breast Cancer Symposium in 2003, represent the first large-scale, multi-center validation of a multi-gene assay.

"The Oncotype DX assay has been extensively evaluated in numerous independent studies involving over 2,600 breast cancer patients, including the large validation study now in the peer-reviewed *New England Journal of Medicine*," said Steven Shak, M.D., chief medical officer of Genomic Health, Inc. "We believe the Oncotype DX assay will become a standard of care in breast cancer, providing critical information to help physicians and patients make potentially life changing treatment decisions," said Dr. Shak.

NSABP and Genomic Health performed a blinded validation trial with prospectively-defined endpoints using surgical tissue samples from 668 tamoxifen-treated patients, who had node-negative, estrogen receptor-positive breast cancer. 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. This was the first time that such a study had been conducted using thin sections from standard diagnostic pathology specimens (fixed paraffin-embedded tissue) that are routinely available. Using quantitative RNA analysis of tumor tissues, the study evaluated the ability of the 21-gene Oncotype DX Recurrence Score assay to determine the likelihood of breast cancer recurrence. The Recurrence Score was able to accurately assign individual patients into high and low risk groups ($p<0.001$), and when the Recurrence Score was examined together with age and tumor size in a multivariate analysis, the Recurrence Score was the strongest independent predictor of recurrence ($p<0.001$).

The NSABP validation study and the NSABP B-20 chemotherapy benefit study looked at a specific population of breast cancer patients, those with node-negative, estrogen receptor-positive tumors who were treated with tamoxifen. This is a substantial patient population, comprising about 50 percent of all newly diagnosed breast cancer patients in the United States each year.

The NSABP validation 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 21-gene panel includes genes related to critical pathways that breast cancer cells depend on, including the estrogen receptor, HER2 and proliferation as well as several other important pathways.

Oncotype DX is the only multi-gene assay currently available to physicians.

"Taken together, these studies conducted by the NSABP in collaboration with Genomic Health have demonstrated that only a subset of patients with early breast cancer identified by Oncotype DX derive benefit from chemotherapy and for those patients the benefit is striking (absolute reduction of the chance of disease recurrence in 10 years of more than 28%)," said Soonmyung Paik, M.D., director of the NSABP Division of Pathology and lead author of the paper published in the *New England Journal of Medicine*. This is a major breakthrough for the individualized treatment of patients diagnosed with early breast cancer," continued Dr. Paik.

"The introduction of the Oncotype DX assay has made individualized medicine a reality today in doctor's offices across the country," said Randy Scott, Ph.D., chairman and CEO of Genomic Health, Inc. "We will continue our research efforts applying sophisticated genomic technology to the fundamental and crucial step of diagnosis in order to continue to make improvements in cancer treatment," said Dr. Scott.

Northern California Kaiser Permanente Study Concurs with NSABP Findings

Northern California Kaiser Permanente presented findings yesterday at the SABCS from a community-based study from 14 Northern California hospitals. These results of the study of 790 cases and controls showed a strong and graded association between the Oncotype DX "Recurrence Score" and 10-year breast cancer mortality ($p<0.001$). The assay provided information that goes beyond tumor size and tumor grade. In addition, the Oncotype DX assay identifies a large proportion of these women who have a very low risk (less than 3 percent) of breast cancer death at 10 years. These new results in a community-based patient population representing approximately one percent of the U.S. population were similar to those from the large clinical validation trial conducted previously by the National Surgical Adjuvant Breast and Bowel Project (NSABP).

NSABP B-14 tamoxifen benefit study

Genomic Health and NSABP studied the tumor tissues from 645 patients in the NSABP B-14 trial, who were treated either with placebo or with tamoxifen, to determine whether the Oncotype DX Recurrence Score assay can predict pure prognosis, responsiveness to hormonal therapy, or both. Results of the study showed that the assay predicts the likelihood of recurrence in node-negative, estrogen receptor-positive breast cancer because it captures both prognosis and the response to hormonal treatment.

Live/Audio Teleconference

A live teleconference featuring speakers from NSABP, NCI, Genomic Health and Y-ME National Breast Cancer Organization will take place Friday, December 10 at 11:45am (Central Time) at the Henry B. Gonzalez Convention Center in San Antonio, TX. For more information about participating in person or by phone please call Kathleen Rinehart at 408/460-9116.

The NSABP is a not-for-profit, clinical trials cooperative group, which includes a network of over 500 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 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. For more information about the company, please visit http://www.genomichealth.com.

# # #