



Genomic Health, Inc. Announces Encouraging Results from Clinical Trials of Genomic Tests to Predict Breast Cancer Recurrence and Response to Chemotherapy and Response to EGFR Inhibitor Therapy in Lung Cancer

--Trials Validate Approach of RNA Analysis in Stored Pathology Tissues; Large-Scale Trials Underway in Breast Cancer Recurrence --

CHICAGO June 2, 2003 — Genomic Health, Inc. today announced encouraging preliminary data in clinical trials using a novel approach to molecular pathology. RNA analysis of thin sections of standard tumor biopsies were used to evaluate panels of genes that may predict breast cancer recurrence and response to chemotherapy as well as response to EGFR inhibitor therapy in lung cancer. Based on promising results, Genomic Health has begun large-scale clinical trials that will examine prospectively-defined endpoints in breast cancer recurrence and plans to conduct similar large-scale trials looking at response to chemotherapy and EGFR inhibitor therapy. Clinical trial findings were presented at the annual meeting of the American Society of Clinical Oncology (ASCO).

Genomic Health has perfected the technology to do genomic analysis in fixed paraffin-embedded tissues (FPET), stored tumor tissue samples collected over the past 20 years. "The feasibility of RNA expression profiling using fixed tumor tissue represents a significant advance," said George Sledge, M.D., professor of medicine, Indiana University. "Instead of waiting years to accumulate fresh tissue and track patient outcomes, Genomic Health's FPET analysis can be performed using routinely stored biopsies from patients with known outcomes therefore accelerating clinical trials," said Dr. Sledge.

Working with its clinical collaborators, Genomic Health has followed a rigorous, phased product development approach. Its technology has been used in numerous clinical trials, four of which were presented at this year's ASCO meeting. Two clinical trials studied breast cancer recurrence (Abstract #3415 and #3416), and one trial looked at response to chemotherapy in breast cancer patients (Abstract #3466). A fourth trial examined a panel of genes that may predict response to EGFR inhibitor (Iressa®) therapy in lung cancer patients (Abstract #763).

Breast Cancer Recurrence and Response to Chemotherapy

Encouraging results from the breast cancer recurrence trials have led Genomic Health to initiate three large-scale clinical trials. Results of these trials are expected within the next 12 months. If validated in large-scale trials, Genomic Health's test could become the first commercially available multi-gene individualized genomic service for cancer patients.

"Until now, the only indications we have had of long-term prognosis in breast cancer were tumor size and the number of involved nodes," said Melody Cobleigh, M.D., oncologist and director of the Comprehensive Breast Cancer Clinic at Rush-Presbyterian-St. Luke's Medical Center in Chicago. "This technology will allow us to tailor a prognosis to an individual patient, using a small panel of genes selected from thousands of genes," said Cobleigh.

It is also important to know which patients are likely to respond to chemotherapy. Genomic Health identified a distinct panel of genes, which, depending on the levels of expression, were correlated with increased or decreased patient response to chemotherapy. Together, recurrence and response to chemotherapy represent a significant step toward individualized therapy.

Response to EGFR Inhibitor Therapy in Lung Cancer

Also presented at ASCO was a study that identified a panel of genes that correlated with tumor response to EGFR inhibitor therapy in lung cancer patients. This research, conducted and presented by Dr. David Agus, Research Director of the Louis Warschaw Prostate Cancer Center at Cedars-Sinai Medical Center, and Dr. Ronald Natale, Acting Medical Director of the Cedars-Sinai Comprehensive Cancer Center, showed that the approach developed by Genomic Health may provide information that is critical to determining the appropriate patient for EGFR inhibitor therapy thus maximizing its benefit. Further study on a large scale is necessary to validate these preliminary findings, and Genomic Health is in discussions concerning these trials.

In 2003, the American Cancer Society estimates that cancer will kill 556,500 Americans, and more than 1,300,000 new cancer cases will be diagnosed. Among the many challenges these patients will face, one of the most difficult will be deciding on a treatment approach. The need for better prognostic information in cancer is vital in many circumstances to improving treatment

decisions and disease outcomes. Current treatment practice, with limited understanding of the differences in individual tumors, often leads to undertreatment of some patients and overtreatment of others. Potential new drugs that are designed to provide more targeted treatment offer exciting hope for patients. However, a crucial need in developing and bringing these drugs to market is identifying and testing the patients, who, based on their individual tumor molecular signatures, are most likely to benefit.

"Genomic Health is pioneering the practical application of genomic analysis to the treatment of cancer." said Randy Scott, Ph.D., Chairman and CEO of Genomic Health and co-founder of Incyte, the world's first genomic information business. "We believe that our unique analysis has the potential to unlock the relevant genomic information of each patient and allow individualized treatment of their cancer," said Dr. Scott.

Founded in August of 2000 and located in Redwood City, California, Genomic Health, Inc. is building an oncology-based health care services company for physicians and patients to provide individualized genomic analysis of tumor biopsies. Genomic Health has pioneered the use of high-throughput analysis of fixed paraffin-embedded tissues to obtain and clinically validate genomic information in large-scale clinical trials. Genomic Health is using this extensive clinical experience to develop validated genomic services to provide individualized information on the likelihood of disease recurrence and response to therapy. Genomic Health's goal is 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, JP Morgan, Versant Ventures, Texas Pacific Group and Baker Tisch.

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