



NanoString Technologies Announces Positive Results from First Validation Study of PAM50-based Breast Cancer Assay

Study Establishes Prognostic Performance of NanoString's First Diagnostic Product, Demonstrates NanoString's Assay Provides Significantly More Prognostic Information and Assigns Fewer Patients to Intermediate Risk Group than Genomic Health's Oncotype DX

SEATTLE, Wash. and SAN ANTONIO, Texas – December 8, 2011 – NanoString Technologies, Inc., a privately held provider of life science tools for translational research and developer of molecular diagnostics, today announced positive results from the first clinical validation study of its first *in vitro* diagnostic product, a breast cancer assay based on the PAM50 gene expression signature. The study, which included more than 1,000 samples from the TransATAC study of hormone receptor-positive early stage breast cancer (ESBC), met all primary and secondary endpoints. In addition, the study demonstrated that the prognostic score provided by NanoString's breast cancer assay may have advantages over results provided by the widely used Oncotype DX[®] test offered by Genomic Health, Inc. Results were presented by the study's independent investigators during the 2011 CTSC-AACR San Antonio Breast Cancer Symposium.

The assay in development by NanoString provides a subtype classification based on the fundamental biology of an individual's breast tumor (referred to as intrinsic subtyping), as well as a prognostic score (referred to as the ROR score) that predicts the probability of cancer recurrence over 10 years. Following regulatory approvals, the company intends to make its assay available for use on the nCounter[®] Analysis System in pathology laboratories and medical centers worldwide. The nCounter Analysis System is currently available for Research Use Only.

In this study, the investigators used NanoString's breast cancer assay to analyze material extracted from tumor samples from 1,017 patients in the landmark ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial of which 1,007 (99%) yielded results that met the pre-specified quality control thresholds internal to the nCounter Analysis System. The goals of the prospectively designed study were to determine whether NanoString's assay adds prognostic information to clinical variables and to compare the assay's performance to other assays for breast cancer prognosis, including Genomic Health's Oncotype DX and the IHC4 test developed by the study's independent investigators.

"In our study, NanoString's breast cancer assay added prognostic information to both clinical variables and Oncotype DX results," said Professor Mitch Dowsett, Ph.D., of The Royal Marsden Hospital and a Team Leader at the Breakthrough Breast Cancer Research Centre at The Institute of Cancer Research in London, and the lead investigator collaborating with NanoString on this study. "In the 1,007 samples for which results from both tests are available, the NanoString's PAM50 ROR score provided significantly more prognostic information than the Oncotype DX RS score and assigned fewer patients to the intermediate risk group than Oncotype DX."

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The study indicated that the PAM50 ROR score added prognostic information about distant recurrence to standard pathological variables in all patients ($p < 0.0001$). Similar results were achieved in all three prospectively defined clinically important subsets of patients: node-negative ($p < 0.0001$), node-positive ($p = 0.002$), and HER2-negative ($p < 0.0001$). In addition, the breast cancer intrinsic subtypes as reported by PAM50 have significantly different outcomes when treated with endocrine therapy alone, reinforcing the power of intrinsic subtyping as a descriptor of breast cancer tumor biology.

“This study paves the way for further validation studies that would support regulatory filings for the NanoString breast cancer assay worldwide,” said Wayne Cowens M.D., Chief Medical Officer of NanoString Technologies. “The strength of these results makes it likely that the ROR score and intrinsic subtyping supplied by the PAM50-based test will be shown to be significantly related to 10-year outcome in future validation studies and will be useful tools to physicians making important clinical decisions for women with early stage breast cancer.”

The nCounter Analysis System is a fully automated digital detection and counting system with a very simple workflow. The assay kits contain all the reagents and consumables required to conduct an experiment. Its ability to analyze small samples and its compatibility with a variety of sample types (including Formalin-Fixed, Paraffin-Embedded tissue) make the system useful for exploring a broad range of problems in translational medicine. In addition to gene expression assays, NanoString provides assays for copy number variation and miRNA analysis. More information is available at www.NanoString.com.

About NanoString Technologies, Inc.

NanoString Technologies is a privately held provider of life science tools for translational research and developer of molecular diagnostics. The company’s nCounter® Analysis System is the first and only technology platform to deliver highly multiplexed, direct profiling of individual molecules in a single reaction without amplification. The nCounter Analysis System offers a cost-effective way to easily profile hundreds of gene transcripts, copy number variations, or miRNAs simultaneously with high sensitivity and precision. The company’s technology enables a wide variety of basic research and translational medicine applications, including biomarker discovery and validation. NanoString is also developing the technology for use in molecular diagnostics.

About the TransATAC Study

TransATAC is a study, funded by Breakthrough Breast Cancer and AstraZeneca, that has used the tissue and data from the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial to analyze the molecular characteristics of patient’s tumor samples in order to develop tailored treatment strategies.

The nCounter platform is for Research Use Only. Not for use in diagnostic procedures.

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