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# Data Supporting Utility of the PAM50 Assay for Breast Cancer Gene Expression Profiling to be Presented at ASCO

NanoString Technologies Developing Distributed Assay Platform for Potential Use in Clinical Diagnostics

SEATTLE, Wash., and CHICAGO, Ill | June 3, 2011 - NanoString Technologies, Inc., a privately held provider of life science tools for translational research and developer of molecular diagnostics, today announced that researchers will present additional evidence for the potential utility of profiling breast cancer based on the PAM50 gene signature at the 2011 American Society of Clinical Oncology (ASCO) annual meeting taking place in Chicago, Illinois from June 3-7.

NanoString announced in December 2010 that it had secured an exclusive worldwide license for the PAM50 gene signature from Bioclassifier, LLC to develop *in vitro* diagnostic and research products for breast cancer on its nCounter® Analysis System. The Bioclassifier team, a partnership of cancer experts from four leading research institutions, and their collaborators will present their most recent findings in five presentations. Highlights include the following:

**Title:** **Using the PAM50 breast cancer intrinsic classifier to assess risk in ER+ breast cancers: A direct comparison to Onco*type* DX**

**Session:** Predictive Markers in Breast Cancer: How Many Tests Do We Need, and What Do They Tell Us?

**Type:** Clinical Science Symposium

**Abstract:** 503

**Date/Time:** Sunday, June 5, 4:30-6:00 PM Central Time

**Location:** McCormick Place Hall B1

**Title:** **The responsiveness of intrinsic subtypes to adjuvant anthracyclines versus nonanthracyclines in NCIC.CTG MA.5 randomized trial**

**Session:** Breast Cancer – Triple-negative/Cytotoxics/Local Therapy

**Type:** Poster Discussion Session

**Abstract:** 1032

**Date/Time:** Saturday, June 4, 5:00-6:00 PM Central Time

**Location:** McCormick Place E450b

The authors of abstract #503 conclude that “the PAM50 Breast Cancer Intrinsic Classifier and Onco*type* DX use different gene sets and algorithms, however, there is a very large and significant overlap in the ability of these clinical tests to determine risk in ER+ breast cancers.” In a previous analysis of the same study presented at the IMPAKT Breast Cancer Conference, the authors also concluded that “half (51%) of the Intermediate RS cancers were re-categorized as low risk “Luminal A” cancers by the PAM50.”

The authors of Abstract #1032 conclude that “across the intrinsic subtypes, HER2-E assignment strongly predicted anthracycline-sensitivity...Strikingly, the chemotherapy-sensitive Basal-like tumors showed no benefit for CEF, suggesting that non-anthracycline regimens should be further investigated in this subtype.”

Philip Bernard, M.D., Associate Professor in the Department of Pathology at the University of Utah/Huntsman Cancer Institute, co-founder of Bioclassifier, LLC and co-author on five studies on the PAM50 gene signature being presented at the ASCO meeting commented: “The PAM50 signature has reproducibly identified prognostic and predictive breast cancer subtypes across multiple cohorts, platforms, and methods of procurement (fresh-frozen and FFPE). Although additional validation in other clinical trials are ongoing, our data shows that the PAM50 assay provides independent prognostic and predictive

information over the standard of care for risk stratification and treatment decision-making in breast cancer."

Additional presentations of clinical research using the PAM50 assay by members of Bioclassifier, LLC include:

**Title: Concordance among gene-expression-based predictors for ER-positive breast cancer treated with adjuvant tamoxifen**

**Session:** Predictive Markers in Breast Cancer: How Many Tests Do We Need, and What Do They Tell Us?

**Type:** Clinical Science Symposium

**Abstract:** 502

**Date/Time:** Sunday, June 5, 4:30-6:00 PM Central Time

**Location:** McCormick Place Hall B1

**Title: PAM50 breast cancer intrinsic classifier: Clinical validation of a multianalyte laboratory developed test**

**Session:** Tumor Biology

**Type:** General Poster Session

**Abstract:** 10597

**Date/Time:** Monday, June 6, 8:00 AM-12:00 PM Central Time

**Location:** McCormick Place Hall A

**Title: Determining agreement between immunohistochemistry and RT-qPCR for standard biomarkers in breast cancer: Validation on GEICAM 9906 clinical trial**

**Session:** Breast Cancer – HER2/ER

**Type:** General Poster Session

**Abstract:** 611

**Date/Time:** Monday, June 6, 1:00-5:00 PM Central Time

**Location:** McCormick Place Hall A

The PAM50 gene signature provides subtype classification and a prognostic score based on the fundamental biology of an individual's breast tumor (referred to as intrinsic subtyping). This information cannot be gained through other currently available diagnostic tests and may provide clinically useful information for a broader range of breast cancers, including classification of tumors from patients with estrogen receptor negative, or node positive tumors.

"We are encouraged to see the substantial body of evidence on the potential clinical utility of intrinsic subtyping breast cancer via the PAM50 gene signature continues to grow," said Brad Gray, President and CEO of NanoString Technologies. "We look forward to collaborating with leading breast cancer researchers to further demonstrate the clinical utility of the PAM50 signature, and to making this assay available on the nCounter platform to the pathology laboratories and medical centers worldwide, following regulatory approvals."

The company's executive management team will be attending this week's ASCO conference to discuss its plans for its breast cancer assay with experts in the field, and to identify other potential partners for its future molecular diagnostics platform.

The nCounter Analysis System is a fully automated digital detection and counting system with a very simple workflow. The assay kits contain all of the reagents and consumables required to conduct an experiment. Minimal sample input requirements and compatibility with a variety of sample types (including Formalin-Fixed, Paraffin-Embedded tissue), extends the utility of the platform. In addition to gene expression assays, NanoString provides assays for copy number variation and miRNA analysis.

The nCounter Analysis System is currently available for Research Use Only.

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.

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