NanoString Technologies Announces Prosigna Presentations at the 2014 CTRC-AACR San Antonio Breast Cancer Symposium

SEATTLE--(BUSINESS WIRE)-- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that multiple posters for the Prosigna® Breast Cancer Gene Signature Assay based on PAM50 will be presented at the 37th Annual CTRC-AACR San Antonio Breast Cancer Symposium (SABCS). These include a prospective study of the Prosigna Assay on adjuvant clinical decision-making in women with Estrogen Receptor-Positive (ER+), HER2-negative, node-negative breast cancer. This decision impact study, performed in conjunction with Grupo Español de Investigación del Cáncer de Mama (GEICAM), a Spanish breast cancer research group, is the first of its kind to provide insights into the changes in clinical practice derived from the use of the Prosigna Assay.

Other posters accepted for presentation at SABCS will highlight studies involving the Prosigna Assay and the PAM50 gene signature, including the UK-based OPTIMA-Prelim trial, in which several multi-parameter tests were compared for concordance of risk stratification and potential for cost-effectiveness in node-positive breast cancer.

The following Prosigna and PAM50 gene signature posters will be presented at SABCS:

Data Posters

- **Session #:** Poster Session 6, P6-08-10  
  **Abstract Title:** Prospective study of the impact of the Prosigna™ assay on adjuvant clinical decision-making in women with estrogen receptor-positive, HER2-negative, node-negative breast cancer: A GEICAM study  
  **Location:** Hall C  
  **Time:** Saturday, December 13, 2014, 7:30 am - 9:00 am

- **Session #:** Poster Session 6, P6-01-06  
  **Abstract Title:** Feasibility of the Prosigna™ multigene test in core biopsies and comparison to corresponding surgical breast cancer sections  
  **Location:** Hall C  
  **Time:** Saturday, December 13, 2014, 7:30 am - 9:00 am

- **Session #:** Poster Session 4, P4-11-07  
  **Abstract Title:** Comparison of multiparameter tests in the UK OPTIMA-Prelim trial  
  **Location:** Halls A-B  
  **Time:** Friday, December 12, 2014, 7:30 am - 9:00 am

- **Session #:** Poster Session 6, P6-08-11  
  **Abstract Title:** UK OPTIMA-prelim study demonstrates economic value in more clinical evaluation of multi-parameter prognostic tests in early breast cancer  
  **Location:** Hall C  
  **Time:** Saturday, December 13, 2014, 7:30 am - 9:00 am

Ongoing Trial Posters

- **Session #:** Poster Session OT3, OT3-2-03  
  **Abstract Title:** Prospective observational study of clinical outcomes for the NanoString® Technologies Prosigna™ test by the West German Study Group  
  **Location:** Halls A-B  
  **Time:** Friday, December 12, 2014, 5:00 pm - 7:00 pm

- **Session #:** Poster Session OT3, OT3-2-06  
  **Abstract Title:** NEOPAL: A randomized phase II study comparing RCB response to neoadjuvant chemotherapy or letrozole-palbociclib in PAM50 defined postmenopausal luminal breast cancer  
  **Location:** Halls A-B  
  **Time:** Friday, December 12, 2014, 5:00 pm - 7:00 pm
About the Prosigna® Breast Cancer Prognostic Gene Signature Assay and nCounter® Dx Analysis System

The Prosigna® Assay provides a risk category and numerical score for assessment of the risk of distant recurrence of disease at 10 years in postmenopausal women with node-negative (Stage I or II) or node-positive (Stage II), hormone receptor-positive (HR+) breast cancer. Based on the PAM50 gene signature initially discovered by Charles Perou, Ph.D. and colleagues, the Prosigna® Assay is an in vitro diagnostic tool that utilizes gene expression data weighted together with clinical variables to generate a risk category and numerical score to assess a patient’s risk of distant recurrence of disease. The Prosigna® Assay measures gene expression levels of RNA extracted from formalin-fixed paraffin embedded (FFPE) breast tumor tissue previously diagnosed as invasive breast carcinoma.

The Prosigna® Assay requires minimal hands-on time and runs on NanoString's proprietary nCounter® Dx Analysis System, which offers a reproducible and cost-effective way to profile many genes simultaneously with high sensitivity and precision.

The nCounter® Dx Analysis System is a highly automated and easy-to-use platform that utilizes a novel digital barcoding chemistry to deliver high precision multiplexed assays. The system is available in the multi-mode FLEX configuration, which is designed to meet the needs of high-complexity clinical laboratories seeking a single platform with the flexibility to run the Prosigna Breast Cancer Assay and, when operated in the “Life Sciences” mode, process translational research experiments and multiplexed assays developed by the laboratory.

In the United States, the Prosigna Assay is available for diagnostic use when ordered by a physician. The Prosigna® Assay has been CE-marked and is available for use by healthcare professionals in the European Union and other countries that recognize the CE Mark, as well as Canada and Australia.

The Prosigna® Breast Cancer Prognostic Gene Signature Assay Intended Use:

In the U.S., the Prosigna® Assay is indicated in female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care, either as:

(1) a prognostic indicator for distant recurrence-free survival at 10 years in postmenopausal women with Hormone Receptor-Positive (HR+), lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinico-pathological factors or (2) a prognostic indicator for distant recurrence-free survival at 10 years in postmenopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1-3 nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinico-pathological factors. The device is not intended for patients with 4 or more positive nodes. The Prosigna® Assay is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients.

For more information, please visit www.prosigna.com.

About NanoString Technologies, Inc.

NanoString Technologies provides life science tools for translational research and molecular diagnostic products. The company’s nCounter Analysis System has been employed in life sciences research since it was first introduced in 2008 and has been cited in over 500 peer-reviewed publications. The nCounter® Analysis System offers a cost-effective way to easily profile the expression of hundreds of genes, miRNAs, or copy number variations, simultaneously with high sensitivity and precision, facilitating a wide variety of basic research and translational medicine applications, including biomarker discovery and validation. The company’s technology has now been applied to diagnostic use. The Prosigna Breast Cancer Prognostic Gene Signature Assay together with the nCounter® Dx Analysis System is FDA 510(k) cleared for use as a prognostic indicator for distant recurrence of breast cancer.

For more information, please visit www.nanostring.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential use of the Prosigna® Assay to change clinical decision-making in the treatment of certain breast cancer patients. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with keeping pace with rapidly changing technology and customer requirements; risks regarding the company’s ability to successfully introduce new products; risks that new market opportunities may not develop as quickly as expected; risks associated with competition in marketing and selling products; risks of increased regulatory requirements; risks associated with obtaining reimbursement coverage for Prosigna; as well as the other risks set forth in the company’s filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. NanoString Technologies disclaims any obligation to update these forward-
Looking statements.

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