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Prosigna Breast Cancer Assay Outperforms All Other Commercial Assays Tested in Updated Analysis of TransATAC Study Presented at the 39th Annual CTRC-AACR San Antonio Breast Cancer Symposium

Prosigna Provides the Most Prognostic Information of Four Genomic Tests in Head-to-Head Comparison of Early Breast Cancer Node-Negative Patients Over a 10-Year Period

SEATTLE, Dec. 12, 2016 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today highlighted study findings relating to the prognostic value of the PAM50-based Prosigna® Breast Cancer Gene Signature Assay in treating breast cancer that were presented at the 2016 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS). Investigators retrospectively evaluated and compared the performance of four multigene expression profiles to predict the risk of Distant Recurrence (DR) in the same large dataset of more than 800 patients from the TransATAC study. These signatures included Prosigna,

Oncotype DX®, EndoPredict® and Breast Cancer IndexSM.

For post-menopausal women with node-negative, hormone receptor-positive, HER2-negative early stage breast cancer, the study found that Prosigna provided the most accurate prognostic information of all four multigene expression profiles tested as measured by the statistical measure known as the likelihood ratio. The study further found that Prosigna also provided the most accurate differentiation between low and high risk patients as compared to the other genomic tests. Low-risk women as identified by Prosigna had a 3% risk of DR over 10 years, the lowest rates of DR for all genomic tests that were studied. In contrast, high-risk women as identified by Prosigna had on average a 33% chance of distant recurrence by 10 years.

These results support the conclusions of the 2016 evidence-based ASCO guidelines that multi-gene expression signatures provide clinical utility for selection of low risk patients who may be spared adjuvant chemotherapy based upon their outcomes when treated with hormone therapy alone. Those guidelines gave a strong recommendation for Prosigna, equivalent to the recommendation given for Oncotype Dx and stronger than other tests evaluated by the guideline committee.

Additional results from the study demonstrated the potential clinical utility of Prosigna for informing the duration of endocrine therapy by accurately assessing the risk of a patient's cancer recurring between five and 10 years after diagnosis. In nodenegative patients, Prosigna provided the most prognostic information between 5 and 10 years after diagnosis as measured by the likelihood ratio. Low-risk women as identified by Prosigna had a 1.4% risk between years 5 and 10, the lowest rates of DR for all genomic tests that were studied.

"This important data demonstrates the ability of Prosigna to identify a low risk group of women for whom adjuvant chemotherapy following surgery and extended endocrine therapy in years 5-10 following diagnosis may be of limited benefit," said Dr. Aleix Prat, MD, Ph.D., from Hospital Clinic in Barcelona, Spain, who was not an investigator on the study.

"These results further validate the clinical utility of Prosigna as a superior second generation breast cancer assay that provides oncologists and patients the critical information they need to make informed decisions about their treatment options," stated Brad Gray, president and chief executive officer of NanoString Technologies.

Results of the TransATAC analysis were presented on Friday December 9th by Ivana Sestak Ph.D. in SABCS abstract S6-05, titled Comprehensive comparison of prognostic signatures for breast cancer in TransATAC. Prosigna's performance as part of the TransATAC study has been previously published in the Journal of Clinical Oncology (http://ascopubs.org/doi/abs/10.1200/jco.2012.46.1558) and the Journal of the National Cancer Institute (http://inci.oxfordjournals.org/content/105/19/1504).

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 510(k) cleared for use on the nCounter Dx Analysis System, and 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, Israel, Australia, New Zealand, Argentina, Thailand, South Africa, Turkey and Hong Kong. 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 clinicopathological 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 clinicopathological factors. The device is not intended for patients with four or more positive nodes.

Other uses of Prosigna or the PAM50 panel in studies as described in this press release are for Investigational Use Only, or Research Use Only.

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 clinical utility of the Prosigna Assay, including its ability to outperform certain other diagnostic tests. These forward-looking statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described or implied in the forward-looking statements. Such risks and uncertainties include, but are not limited to: risks associated with keeping pace with rapidly changing technology and customer requirements; risks associated with competition in marketing and selling products; risks of increased regulatory requirements; risks associated with maintaining and expanding reimbursement coverage for Prosigna; risks related to the Company's intellectual property portfolio, 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.

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 more than 1,350 peer-reviewed publications. The nCounter Analysis System offers a cost-effective way to easily profile the expression of hundreds of genes, proteins, 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 is also being used in diagnostics. 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. In addition, the company is collaborating with multiple biopharmaceutical companies in the development of companion diagnostic tests for various cancer therapies, helping to realize the promise of precision oncology.

For more information, please visit <u>www.nanostring.com</u>.

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