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## **American Society of Clinical Oncology (ASCO) Clinical Practice Guideline Recommends Use of Prosigna (PAM50) for Guiding Treatment Decisions in Early Stage Breast Cancer Patients**

### **Prosigna One of Only Two Assays to Receive Strong Recommendation Together With High Rating of Evidence Quality**

SEATTLE, Feb. 09, 2016 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that the updated American Society of Clinical Oncology (ASCO) Clinical Practice Guideline on the appropriate use of breast tumor biomarker assay results recommends the use of the Prosigna® Breast Cancer Prognostic Gene Signature Assay (PAM50) to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer with known hormone receptor and HER2 status. The Prosigna assay was one of only two such assays to receive a "high" rating of evidence quality together with a "strong" recommendation.

"Prosigna's inclusion in the ASCO Clinical Practice Guideline, specifically for use in guiding decisions on adjuvant systemic therapy for women with early stage breast cancer, places Prosigna on equal footing with the Oncotype DX® test," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "This is the sixth major breast cancer treatment guideline to include Prosigna in the past twelve months, and it further strengthens our case for reimbursement and market adoption."

The ASCO Clinical Practice Guideline provides evidence-based recommendations based on a comprehensive review and analyses of the relevant literature for each recommendation. The Guideline states that if a patient has hormone receptor-positive, HER2-negative (node-negative) breast cancer, the clinician may use the PAM50 (Prosigna) risk of recurrence (ROR) score, known as the Prosigna Score in the United States, in conjunction with other clinicopathologic variables, to guide decisions on adjuvant systemic therapy.

"We applaud the rigorous scientific methodology and transparency that the ASCO multidisciplinary expert breast cancer panel applied in reviewing and weighing the available scientific evidence," said Alessandra Cesano, M.D., Ph.D., Chief Medical Officer of NanoString. "By focusing on the clinical utility of sparing women unnecessary chemotherapy, the Committee has helped future breast cancer patients avoid the risk of fatal, life-threatening, or permanently changing toxicities."

The Guideline, together with additional information including details of the methodology and review of the scientific literature, is available at: <http://www.instituteforquality.org/use-biomarkers-guide-decisions-adjuvant-systemic-therapy-women-early-stage-invasive-breast-cancer>.

#### **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, Israel, Australia, New Zealand 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.

For more information, please visit [www.prosigna.com](http://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 more than 1,000 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 [www.nanostring.com](http://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 impact of inclusion in the ASCO Clinical Practice Guideline on the reimbursement and market adoption for Prosigna and on treatment decisions made by breast cancer patients and their physicians.*

*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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