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# NanoString Announces Publication in the Journal of Clinical Oncology Showing the Prosigna Assay Identifies Women With a Low Risk of Late Distant Recurrence of Breast Cancer

SEATTLE--(BUSINESS WIRE)-- NanoString Technologies, Inc., (NASDAQ:NSTG) a provider of life science tools for translational research and molecular diagnostic products, today announced that the *Journal of Clinical Oncology* published an analysis of data in over 2,100 patients showing that the risk-of-recurrence (ROR) score generated by the PAM50-based Prosigna<sup>TM</sup> Brea Cancer Assay predicts the risk of late distant recurrence, after five years of endocrine therapy, in postmenopausal women with Hormone Receptor-Positive (HR+) early-stage breast cancer. These results, in combination with previously published clinical studies, demonstrate the potential for Prosigna to inform both the use of adjuvant chemotherapy and the use of extended adjuvant endocrine therapy based on a single risk score.

The results were based on the combined analysis of 2,137 postmenopausal women with HR+ early-stage breast cancer enrolled in the Austrian Breast & Colorectal Cancer Study Group 8 (ABCSG-8) and Trans-Arimidex, Tamoxifen, Alone or in Combination (TransATAC) studies. The results also showed that Prosigna could identify a patient population where the risk of late distant recurrence is so low that additional hormonal treatment may not be warranted.

The American Society for Clinical Oncology (ASCO) Cancer Treatment Guidelines were recently updated to extend the recommended duration of endocrine therapy to 10 years for most women, suggesting that prolonged treatment is generally associated with better outcomes. Given the recommendations for longer durations of therapy, it was acknowledged in the ASCO update that there is a need to identify strategies that are likely to promote the use of effective endocrine treatments among women, including the use of molecular diagnostic assays.

"Better tools for informing the important decision of endocrine therapy duration are urgently needed. Not only does this data establish the Prosigna Assay as a clinically meaningful test for determining risk of late recurrence, it shows that Prosigna is capable of providing prognostic information for both 10-year distant recurrence and late distant recurrence," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "The publication of this compelling data is a yet another testament to the leadership and achievements of the late Dr. Wayne Cowens, who led the unique collaboration that made this work possible and to whom the paper is dedicated. We are pleased to honor his legacy through a growing body of clinical evidence that continues to support the success of our Prosigna program."

The combined analysis of 2,137 patients is based on long-term follow-up data and tissue samples from postmenopausal women with HR+ early-stage breast cancer who received five years of endocrine treatment and did not have a recurrence in the first five years following diagnosis. The primary objective of this study was to determine if the Prosigna ROR Score provides prognostic information in the period after the first five years following diagnosis. The time from year five post diagnosis to first distant recurrence was the prospectively defined primary endpoint. Using the Prosigna Assay to generate a Prosigna ROR Score, women categorized into the high-risk group had 16.6 percent risk of distant recurrence in years five to ten, those in the intermediate group had a risk of 8.3 percent, and those categorized into the low risk group had a risk of only 2.4 percent.

"It has been previously shown that the PAM50-based ROR score is significantly correlated with distant recurrence in each of the TransATAC and ABCSG8 randomized trials," said Ivana Sestak, PhD, Centre for Preventive Medicine, Queen Mary University London and lead investigator of this study. "In the combined analysis, the ROR score significantly improved the accuracy of the prediction of the risk of late distant recurrence when compared to standard clinical and pathological variables in all patients and all subgroups."

Data from this study, titled, "Prediction of Late Distant Recurrence After 5 Years of Endocrine Treatment: A Combined Analysis of Patients From the Austrian Breast and Colorectal Cancer Study Group 8 and Arimidex, Tamoxifen Alone or in Combination Randomized Trials Using the PAM50 Risk of Recurrence Score" were initially presented at the 2013 San Antonio Breast Cancer Symposium. The full manuscript is now published online and can be found at: <a href="http://jco.ascopubs.org/content/early/2014/10/14/JCO.2014.55.6894.full.pdf">http://jco.ascopubs.org/content/early/2014/10/14/JCO.2014.55.6894.full.pdf</a>+html.

# About the Prosigna<sup>™</sup> Breast Cancer Prognostic Gene Signature Assay and nCounter<sup>®</sup> 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<sup>®</sup> 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<sup>™</sup> 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 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 4 or more positive nodes.

## **Special Conditions for Use:**

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 <u>www.prosigna.com</u>.

## 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 550 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 identify patients at risk of late distant disease recurrence and the potential of Prosigna to inform both the use of adjuvant chemotherapy and the use of extended adjuvant endocrine therapy based on a single risk score. 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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