NanoString Announces Largest and Most Comprehensive Study to Date of Prosigna Breast Cancer Assay Published in Journal of Clinical Oncology

February 5, 2018

Comprehensive Study Includes All Danish Women Diagnosed with Breast Cancer from 2000 to 2003 who were Indicated for Prosigna and Treated with Endocrine Therapy

Accompanying Editorial Highlights Encouraging Data on Clinical Utility in Node-Positive Breast Cancer

SEATTLE, Feb. 05, 2018 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced the publication of a landmark study in which Danish researchers used the Prosigna® Breast Cancer Assay risk of recurrence (ROR) score to accurately predict rates of 10-year distant recurrence (DR) of cancer in a comprehensive and population-based cohort including all postmenopausal women in Denmark with early-stage hormone receptor (HR)-positive, Her-2 negative breast cancer who received 5 years of adjuvant endocrine therapy according to nationwide guidelines between 2000 and 2003.

In an article published in the Journal of Clinical Oncology (https://doi.org/10.1200/JCO.2017.74.6586), Laenkholm et al report on a study of 2,558 postmenopausal women identified as having HR positive/HER2-negative, early-stage breast cancer, 1,395 of whom had one to three positive axillary nodes. The authors demonstrated the clinical utility of the Prosigna assay to aid decision-making in relation to the use of adjuvant chemotherapy for both node-negative and node-positive disease. Importantly, 26% of the node-positive patients were categorized as having a low-risk ROR score corresponding to a risk of DR of just 3.5% at 10 years compared with a DR risk of 11.5% and 22% for patients categorized as intermediate or high risk, respectively.

“In this study we were able to demonstrate the clinical utility of Prosigna in a real world setting by testing a comprehensive population-based cohort of patients," stated Dr. Bent Ejlertsen of the Danish Breast Cancer Cooperative Group. “These results have driven us to update our treatment guidelines in Denmark to include testing with Prosigna as part of the workup of postmenopausal women with early stage HR-positive/Her-2 negative breast cancer, including patients with node-positive disease.”

In an editorial accompanying the article (https://doi.org/10.1200/JCO.2017.76.9802), Ricardo Costa of H. Lee Moffitt Cancer Center and William Gradishar of Northwestern University note that the “authors present encouraging data for the clinical utility of molecular assays to aid decision-making for node-positive disease.” In addition, they note that these results are similar to those previously published by Gnant et al (https://doi.org/10.1093/annonc/mdv215), who used the PAM50-based ROR score to analyze tissue samples from patients with node-positive disease who participated in the ABCSG-8 and ATAC trials, and who concluded that PAM50 ROR score “can identify node-positive patient subgroups with limited risk of metastasis after endocrine therapy, for whom adjuvant chemotherapy can be spared.”

“This study demonstrates that Prosigna can reliably identify early stage breast cancer patients who have a low risk-of disease recurrence at 10 years, including a substantial proportion of patients with node-positive disease for whom the risk/benefit derived for adjuvant chemotherapy would be at best neutral,” said Dr. Alessandra Cesano, chief medical officer of NanoString Technologies. “This data supports the value of the Prosigna test in decision-making related to de-escalation of adjuvant chemotherapy in this patient population.”

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 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.

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 1,830 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.

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 value in patient decision-making related to de-escalation of adjuvant chemotherapy in certain patient populations. 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.

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