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ESMO Clinical Practice Guidelines for Breast Cancer Recommend the Use of Prosigna/PAM50 Assay for Determining Potential Benefit From Chemotherapy

SEATTLE, Sept. 9, 2015 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc., (NASDAQ:NSTG) a provider of life science tools for translational research and molecular diagnostic products, today announced that the PAM50 gene signature, commercialized as the Prosigna® Breast Cancer Gene Signature Assay, has been added to the European Society for Medical Oncology (ESMO) Clinical Practice Guidelines. The updated guidelines recognize Prosigna's value to provide additional prognostic and predictive information that complements the pathologic assessment predicting the benefit of adjuvant chemotherapy.

"In cases of clinical uncertainty, the decision to use chemotherapy in early stage breast cancer patients is a challenge. Chemotherapy can have devastating short-term and long-term consequences for many patients and therefore should be used only when we have very good reasons, either related to high risk of relapse or aggressive tumor biology," said Dr. Miguel Martin, Professor of Medicine and Chair of the Spanish Group for Breast Cancer Research-GEICAM. "Prosigna is a new and robust tool to help clinicians assess tumor biology and risk of recurrence, which may help determine the appropriateness of systemic chemotherapy."

Prosigna was acknowledged as having achieved level 1B evidence for its prognostic value and is recommended for use to predict the benefit of chemotherapy. The conclusion of the guideline panel places Prosigna at parity with other established gene expression assays. The updated ESMO Guidelines are consistent with the recently updated St. Gallen International Breast Cancer Guidelines, which both suggest a patient's risk of recurrence should be assessed by tumor biology and burden of disease. Additionally, the ESMO Guidelines indicate that the decision to use systemic adjuvant chemotherapy should be based on the intrinsic subtype, which can be efficiently determined using the CE-marked version of the Prosigna Assay. The guidelines further recommend specific systemic treatment strategies for each identified molecular subtype.

The ESMO Clinical Practice Guidelines are developed by an international panel of experts in accordance with ESMO operating procedure for assessing levels of clinical evidence. The ESMO Clinical Practice Guidelines for Breast Cancer are available at: http://www.esmo.org/Guidelines/Breast-Cancer.

"We're pleased with the decision of the ESMO Clinical Practice Guideline committee to recognize the value of Prosigna for informing the use of chemotherapy in breast cancer," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "This is the third European clinical practice guideline to include Prosigna, and should support our continued success in bringing breast cancer recurrence testing to patients."

About the Prosigna Assay and the 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 or IIIA), 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 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 Assay and, when operated in the "Life Sciences" mode, process translational research experiments and multiplexed assays developed by the laboratory.

The Prosigna Breast Cancer Prognostic Gene Signature Assay Intended Use:

In the European Union, and other countries that recognize the CE mark, as well as Canada and Australia, the Prosigna Assay is indicated in female breast cancer patients who have undergone either mastectomy or breast-conserving surgery in conjunction with locoregional treatment consistent with standard of care, either as:

a. A prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal 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.

b. A prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1-3 positive nodes, or 4 or more positive nodes), Stage II or IIIA breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors.

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 800 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 has also 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 who will respond to chemotherapy and the impact of the ESMO guidelines on the adoption of Prosigna by clinicians in the European market. 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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