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Blue Cross Blue Shield Association Evidence Street Issues Positive Assessment for NanoString's Prosigna® Breast Cancer Assay

SEATTLE, Jan. 10, 2017 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that the Blue Cross Blue Shield Association Evidence Street has issued a positive assessment of the Prosigna® Breast Cancer Gene Signature Assay. Evidence Street pioneered the development of scientific criteria for assessing medical technologies through comprehensive reviews of clinical evidence. The positive Evidence Street assessment is in line with updated ASCO guidelines released in February 2016. The ASCO guidelines recommend the use of the Prosigna Breast Cancer assay to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer with known hormone receptor and HER2 status.

Assessments by Evidence Street provide objective information to those who deliver and manage medical care. These assessments are based on clinical and scientific evidence and evaluate whether a technology improves net health outcomes. Evidence Street does not make local medical policy determinations, however this review is an important step forward in receiving coverage for the Prosigna® Breast Cancer Gene Signature Assay from health insurance providers in the Blue Cross Blue Shield affiliate network.

"A positive Evidence Street assessment for Prosigna will greatly help us in our ongoing discussions with BCBS Health Plans that have not formally issued a positive coverage decision for Prosigna," said Brad Gray, president and chief executive officer of NanoString Technologies. "Our team continues to work with these independent Blue Cross Blue Shield plans to ensure their patients have access to this state-of-the-art test, and we estimate that up to an additional 45 million lives could be covered as local BCBS plans convert in the event all of the remaining BCBS Health Plan provide Prosigna coverage, which would bring Prosigna coverage to over 90% of indicated US patients."

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 1,450 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 impact of a positive Evidence Street assessment of Prosigna on NanoString's ability to gain coverage for Prosigna with the remaining BCBS health plans and on increasing patient access to Prosigna. 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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