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NanoString Technologies Receives Favorable Final Local Coverage Determination by Palmetto GBA for Its Prosigna Breast Cancer Assay

SEATTLE, Aug. 13, 2015 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies through its MolDx program, has issued a favorable final local coverage determination (LCD) for the Prosigna® Breast Cancer Assay.

"We are delighted by the favorable LCD published today by Palmetto's MolDx team. The policy decision is expected to increase patient access across Prosigna's entire intended use population, including patients with both node-negative and node-positive breast cancer," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "The MolDx process is viewed as one of the most sophisticated and influential technology assessments in the US, and the positive MolDx policy demonstrates the effectiveness and impact of our reimbursement team."

The final LCD, which confirms the coverage policy for Medicare beneficiaries, includes reimbursement coverage for postmenopausal patients with ER+, lymph node-negative, stage I or II breast cancer; and ER+, lymph node-positive (1-3 positive nodes), stage II breast cancer. The draft LCD is posted to the Medicare Coverage Database on the Centers for Medicare & Medicaid Services (CMS) website at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36125&ContrId=374&ver=5&ContrVer=1&Date=11%2f01%2f2015&DocID=L36125&bc=iAAAAAgAAAAAAA%3d%3d&

This decision is consistent with the draft guidance issued by Palmetto GBA on May 14. Following a public comment period that ended on July 24, Palmetto GBA finalized and published the guidance, which becomes effective for services on or after October 1, 2015. The final LCD applies to the J11 jurisdiction, comprising North Carolina, South Carolina, Virginia and West Virginia. Other Medicare jurisdictions participating in the MolDx program may choose to adopt the same coverage policy in the future.

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.

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 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 news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our prospects for expanding patient access to Prosigna across Prosigna's intended use population as a result of the Palmetto GBA coverage decision and the potential of this coverage decision to positively influence the coverage policies of other Medicare carriers and private payors. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include market acceptance of our products; delays or denials of reimbursement for diagnostic products; delays or other unforeseen problems with respect to manufacturing, product development or clinical studies; the impact of competition; the impact of expanded sales, marketing, product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks set forth in our 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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