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Humana Issues Positive Coverage Decision for NanoString's Prosigna® Breast Cancer Assay

SEATTLE, Jan. 31, 2017 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that Humana has issued a positive coverage decision for the Prosigna® Breast Cancer Gene Signature Assay. Humana and its more than 13 million members join other payors now covering Prosigna, collectively representing more than 175 million covered lives throughout the United States.

This positive coverage decision is in line with updated ASCO guidelines released in February of 2016, wherein Prosigna is considered medically necessary to assess the necessity of adjuvant chemotherapy in ER-positive, HER2-negative, node-negative breast cancer patients, when adjuvant chemotherapy is not precluded due to any other factor.

"Coverage by Humana is another important milestone in making our Prosigna test available to all indicated patients," said Brad Gray, president and chief executive officer of NanoString Technologies. "Our team has done an outstanding job of working with both national and regional payors to ensure that their patients have access to this state-of-the-art test."

The updated healthcare policy for Humana, which now includes the Prosigna Assay, is available on its website: http://apps.humana.com/tad/tad_new/Search.aspx?criteria=Prosigna&searchtype=freetext&policyType=both

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.

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