United Kingdom's National Institute for Health and Care Excellence (NICE) Recommends NanoString's Prosigna Breast Cancer Gene Signature Assay to Guide Chemotherapy Treatment Decisions for Qualified Early-Stage Invasive Breast Cancer Patients

December 19, 2018

SEATTLE, Dec. 19, 2018 (GLOBE NEWSWIRE) -- NanoString Technologies, Inc. (NASDAQ:NSTG), a provider of life science tools for translational research and molecular diagnostic products, today announced that health officials from the National Institute for Health and Care Excellence (NICE) in the United Kingdom recently issued a recommendation that includes the use of the Prosigna® Breast Cancer Gene Signature Assay result to guide adjuvant chemotherapy decisions for early-stage breast cancer patients.

"NICE's recommendation of Prosigna is an important milestone in achieving in-country delivery of personalized medicine to breast cancer patients in England," said Dr. Alessandra Cesano, chief medical officer of NanoString Technologies. "NICE is broadly considered to be the world leader in the assessment of clinical and cost effectiveness, and the quality and thoroughness of the work supporting the current guidance should be considered a gold-standard approach for the evaluation of diagnostic products worldwide. We could not be more pleased with this outcome and look forward to offering Prosigna through the National Health Service (NHS) in England in 2019."

Andreas Makris, M.D., head of the UK Breast Cancer Group and Consultant Oncologist at the Mt. Vernon Cancer Centre stated, "The NICE decision is an important step forward for breast cancer patients. Clinicians are now able to make their own decision about the most appropriate test for their patients. We are very excited to see that Prosigna is now available as an option for NHS patients."

The updated diagnostics guidance document and other project related materials can be found on the NICE website (www.nice.org.uk/guidance/indevelopment/gid-dg10015). The guidance is expected to become effective as early as December 19, 2018.

Prosigna testing is currently conducted in several laboratories throughout the United Kingdom which are listed in the NanoString website https://www.nanostring.com/diagnostics/prosigna-uk/prosigna-sites. For more information regarding access to Prosigna please contact uk@nanostring.com or +44 1494 590430.

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 or IIIA), 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 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. 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 2,180 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.

The NanoString logo, NanoString, NanoString Technologies, nCounter, and Prosigna are registered trademarks or trademarks of NanoString Technologies, Inc. in various jurisdictions.

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.

Contact:

Doug Farrell
Vice President, Investor Relations & Corporate Communications
dfarrell@nanostring.com
Phone: 206-602-1768

Source: NanoString Technologies, Inc.