



NanoString Technologies Receives Market Approval from the Australian Therapeutic Goods Administration for its Prosigna Breast Cancer Prognostic Gene Signature Assay

The Prosigna Assay is the First Genomic Breast Cancer Diagnostic Test Approved in Australia to Assess a Woman's 10-year Risk of Distant Recurrence

SEATTLE — August 5, 2014 — NanoString Technologies, Inc., (NASDAQ:NSTG) a provider of life science tools for translational research and developer of molecular diagnostic products, today announced that it has received market approval from the Australian Therapeutic Goods Administration (TGA), clearing the company to market its Prosigna™ Breast Cancer Prognostic Gene Signature Assay for assessing a woman's risk of distant recurrence of disease. The Prosigna Assay was launched in the U.S. in December 2013 and is also CE Marked for in vitro diagnostic use in the European Union and Israel, and is licensed for use in Canada.

"The Prosigna Assay continues to gain support in the U.S. and internationally as regulatory bodies recognize Prosigna's strong clinical and analytical validation," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "With Australian market authorization, which mirrors the CE-marked Prosigna Assay for the European Union and Israel, we are enabling clinical labs in Australia to generate critical information to help doctors and their patients make important breast cancer treatment decisions."

Prosigna is an *in vitro* diagnostic breast cancer assay run on the nCounter® Dx Analysis System that assesses the gene expression profile of cells found in a woman's breast cancer tissue. This information is then used to identify intrinsic subtype of the tumor and assess the risk of distant recurrence of disease in postmenopausal women with hormone receptor-positive (HR+) early-stage breast cancer. The Prosigna Assay is the first diagnostic test for breast cancer approved by TGA for use in local, qualified clinical laboratories, enabling oncologists and pathologists to meet the diagnostic needs of patients with breast cancer without sending tissue samples outside of Australia.

The Prosigna Assay offers key features to molecular technicians and clinicians in Australia, including:

- Identification of intrinsic subtype and individualized estimate of distant recurrence risk.
- All-in-one assay consumables, allowing laboratories to test as little as a single section of formalin-fixed paraffin embedded (FFPE) tumor tissue.
- High-throughput workflow allowing each nCounter Dx Analysis System to process up to 30 patient samples per eight hour work day.

"Expanding global availability of Prosigna is an important part of our long-term growth strategy for this breast cancer diagnostic," said Bruce Seeley, Senior Vice President and General Manager of Diagnostics at NanoString Technologies. "By simplifying and decentralizing genomic testing, we believe the Prosigna Assay will provide physicians worldwide with more important clinical information while ensuring broader patient access. Most importantly, breast cancer patients in Australia will now have access to an innovative new genomic test that can be performed locally."

The Prosigna assay was clinically validated in two studies, including the TransATAC and ABCSG-8 studies, which included more than 2,400 patient samples.

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 500 peer-reviewed publications. The nCounter Analysis System offers a cost-effective way to easily profile the expression of hundreds of genes,

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 now 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 adoption of Prosigna by Australian physicians, patients, and clinical laboratories and our ability to obtain additional regulatory approvals for Prosigna in other countries. 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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