



NanoString Technologies Receives Canadian Market Approval for its Prosigna Breast Cancer Prognostic Gene Signature Assay

The Prosigna Assay on the nCounter Dx Analysis System Provides Compelling Clinical Data, Clear Patient Report, and Localized Processing in Qualified Canadian Labs

SEATTLE — May 6, 2014 — NanoString Technologies, Inc., (NASDAQ:NSTG) a provider of life science tools for translational research and molecular diagnostic products, today announced that it has received a Class III Medical Device License from Health Canada, clearing the company to market its Prosigna[®] Breast Cancer Prognostic Gene Signature Assay for assessing a woman's 10-year risk of distant recurrence and accurately identifying the intrinsic biologic subtype of the tumor.

"With Canadian market authorization, which mirrors the CE-marked Prosigna Assay approved for the European Union and Israel, we are enabling clinical labs in Canada to generate critical information to help doctors and their patients make important breast cancer treatment decisions," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "We will continue to seek regulatory approvals for Prosigna, expanding its availability worldwide and providing greater access to sophisticated genomic tests for patients battling breast cancer regardless of their geographic location."

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 approved by Health Canada 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 Canada.

Canadian research institutes played a critical role in the discovery and development of the PAM50 gene signature, a gene set that serves as the basis for the Prosigna Assay and is used for gene expression based subtyping.

"The Prosigna Assay is the result of a decade of research, in which Canadian researchers have had a major role as co-inventors and leaders in multinational research and development programs," said Torsten Nielsen, M.D., Ph.D., who is a pathologist at the BC Cancer Agency and the Genetic Pathology Evaluation Centre at Vancouver General Hospital. Dr. Nielsen is also co-inventor of the PAM50 gene signature. "I would particularly like to thank my colleagues at the BC Cancer Agency and the NCIC-Clinical Trials Group who have contributed to important research that has demonstrated the value of Prosigna. Health Canada approval means this test can now be considered for Canadian patients battling breast cancer, using local laboratory facilities with clinically certified accuracy."

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

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

- Identification of intrinsic subtype and individualized estimate of distant recurrence risk.
- All-in-one assay consumables, including RNA extraction kits, 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.

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), 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 Canada, the European Union, and other countries that recognize the CE mark, 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:

- a. A prognostic indicator for distant recurrence-free survival at 10 years in postmenopausal women with 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 postmenopausal women with 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 more than 400 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 Canadian 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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