NanoString Technologies Receives FDA 510(k) Clearance for Prosigna™ Breast Cancer Prognostic Gene Signature Assay

Business Wire

NanoString Technologies, Inc., a provider of life science tools for translational research and molecular diagnostic products, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Prosigna ™ Breast Cancer Prognostic Gene Signature Assay. Based on the PAM50 gene signature, Prosigna is the company's first FDA-cleared in vitro diagnostic assay and uses the gene expression profile of cells found in breast cancer tissue to assess a patient's risk of distant recurrence of disease. The Prosigna Assay is performed using the nCounter ® Dx Analysis System, which can be placed in qualified laboratories throughout the United States, empowering oncologists and pathologists to quickly and easily meet the testing needs of their breast cancer patients.

"Receipt of FDA 510(k) clearance for Prosigna marks a key milestone for NanoString and is an important step forward in the treatment of breast cancer. This achievement is a testament to the ongoing dedication and professionalism of our team, and the commitment of our collaborators," said Brad Gray, President and Chief Executive Officer of NanoString Technologies. "Prosigna illustrates our approach of using nCounter technology to translate genomic discoveries into powerful in vitro diagnostic products, and it represents a significant growth opportunity beyond our robust life sciences research business." The Prosigna Assay is intended for use as a prognostic indicator for distant recurrence-free survival at 10 years, and is indicated for postmenopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (one to three positive nodes) hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. For each patient, the Prosigna Assay reports the Prosigna Score (referred to as Risk of Recurrence Score, or ROR Score, in the scientific literature, including the TransATAC study recently published in the Journal of Clinical Oncology1) and a risk category based on both the Prosigna Score and nodal status. Node-negative patients are classified as low, intermediate or high risk, while node-positive patients are classified as low or high risk.

Other key features of the Prosigna Breast Cancer Prognostic Gene Signature Assay include: 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 Automated generation of personalized full-color patient reports that can be quickly and easily shared electronically with ordering oncologists Bruce Seeley, Senior Vice President & General Manager of Diagnostics of NanoString Technologies commented: "We believe that the compelling clinical data, clear patient reporting, and unique

delivery model position Prosigna for success in the U.S. market. By integrating the Prosigna Assay into existing laboratory workflows, we are offering physicians and patients seamless and timely access to clinical insights and a powerful tool that can aid in making more informed treatment decisions." Prosigna-enabled nCounter Dx Analysis Systems are expected to be available for placement in high-complexity Clinical Laboratory Improvement Amendments (CLIA) certified laboratories late in the fourth quarter of 2013. Prosigna testing services are expected to be available through qualified U.S. clinical laboratories beginning in the first quarter of 2014.

Conference Call NanoString management will host an investment community conference call on Tuesday September 10 beginning at 5:30am PT / 8:30am ET to discuss these developments. Individuals interested in listening to the conference call may do so by dialing (888) 793-9492 for domestic callers, or (734) 385-2643 for international callers, or from the webcast on the investor relations section of the company's website at: www.nanostring.com. The webcast will be available on the company's website for 14 days following the completion of the call.

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