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Veracyte Announces Publication of Nearly 700-Patient Study Using Prosigna Breast Cancer Test to Identify Patients Likely to Benefit from Aggressive Chemotherapy

Findings Based on Randomized Study of Danish Women with High-Risk, Early Breast Cancer Published in *npj Breast Cancer*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Veracyte, Inc., (Nasdaq: VCYT) today announced the publication of a large, retrospective study in which the Danish Breast Cancer Group (DBCG) used the Prosigna® breast cancer prognostic gene signature assay to identify which women were more likely to benefit from aggressive chemotherapy based on their intrinsic breast cancer subtype. The findings appear online in *npj Breast Cancer*, a peer-reviewed open-source journal, and suggest that women with HER2-enriched subtypes may benefit from commonly used anthracycline-containing chemotherapy regimens, while those with luminal breast cancer subtypes – which accounted for 30 percent of the women in the study – could potentially be spared such treatment regimens, which have significant cardiotoxicity in some patients.

The findings are from a retrospective analysis of the DBCG89D trial – a prospectively designed, randomized trial of 980 pre- and post-menopausal Danish women with early-stage breast cancer who were administered adjuvant chemotherapy regimens that contained anthracycline (epirubicin) or were CMF- (cyclophosphamide, methotrexate and fluorouracil) based. Among the 686 women with Prosigna results, overall survival was significantly different in anthracycline- versus non-anthracycline treated patients with HER2-enriched (Hazard Ratio of 0.72, 95% Confidence Interval 0.52; 0.99) tumors, but not in patients with luminal A (Hazard Ratio of 1.62, 95% Confidence Interval 0.97; 2.71) or luminal B (Hazard Ratio of 1.41, 95% Confidence Interval 0.80; 2.47) cancers. Of the 686 women with Prosigna results, the test identified 132 women with luminal A, 78 with luminal B, 259 with basal-like and 217 with HER2-enriched breast cancer subtypes.

"Our study was a carefully planned, formal re-analysis of an important Danish clinical trial that helped establish the use of anthracycline chemotherapies in breast cancer -- an aggressive treatment that saves lives but can have serious side effects, including heart damage," said Torsten Nielsen, M.D., Ph.D., professor of pathology and laboratory medicine at BC Cancer, the University of British Columbia, a co-author of the study and a developer of the gene signature on which the Prosigna test is based.

"By applying Prosigna technology, which had not yet been invented when the tumor tissue from this trial was originally collected and stored, we found that patients with luminal subtypes did not benefit from putting anthracycline drugs into the chemotherapy regimen. These drugs only provided added benefit to those with non-luminal molecular subtypes. The study contributes to the accumulating body of evidence that the breast cancer molecular subtypes and risk scores identified with Prosigna technology can help identify which women can safely back off of aggressive chemotherapy."

The Prosigna test uses advanced genomic technology to inform next steps for patients with early-stage breast cancer, based on the genomic make-up of their disease. The test analyzes the activity of 50 genes known as the PAM50 gene signature, along with clinical-pathological features, and can provide a hormone-receptor positive early breast cancer patient and her physician with a prognostic score indicating the probability of cancer recurrence during the next 10 years. Outside of the United States, it is also utilized to provide PAM50 molecular subtype information.

"These new data suggest that the Prosigna test may be able to offer new levels of individualized treatment for women with early-stage breast cancer, potentially enabling many to avoid more aggressive chemotherapy regimens," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "These findings also suggest exciting future expansion opportunities for the Prosigna test's positioning in global markets where intrinsic breast cancer subtypes are reported in the test results."

Veracyte acquired the Prosigna test from NanoString Technologies, Inc. in December 2019 as part of its acquisition of the exclusive global diagnostic rights to the nCounter® FLEX Analysis System. The DBCG retrospective study was supported by funds from NanoString Technologies.

About the Prosigna Breast Cancer Prognostic Gene Signature Assay

Physicians use Prosigna to help guide therapeutic decisions so that patients receive therapeutic interventions, such as chemotherapy, only if clinically warranted. The *in vitro* diagnostic test 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 ten 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; or
2. A prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1-3 positive 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 4 or more positive nodes.

The Prosigna test is FDA 510(k) cleared in the United States for use on the nCounter Dx Analysis System and is available for use when ordered by a physician. The test is performed on formalin-fixed and paraffin-embedded tissue. The Prosigna test has been CE-marked, showing that it conforms with European Union regulations, and is available for use by healthcare professionals in the European Union and other countries that recognize the CE mark, as well as in Canada, Israel, Australia, New Zealand and Hong Kong. The test is covered by Medicare and leading private payers in the United States and is widely covered by government and private payers in the countries where it is available.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing answers to clinical questions that inform diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. The company's core products are uniquely developed with RNA whole-transcriptome sequencing and machine learning to deliver results that give patients and physicians a clear path forward. Since its founding in 2008, Veracyte has commercialized seven genomic tests and is transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. In December 2019, Veracyte acquired the exclusive global diagnostic rights to the nCounter platform from NanoString Technologies, Inc., through which it plans to make its genomic tests available to physicians and their patients worldwide. These include commercial and in-development tests in breast cancer and lymphoma, respectively, which Veracyte also acquired through the transaction. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding Veracyte's expectations regarding the ability of the Prosigna breast cancer prognostic gene signature assay to reduce unnecessary anthracycline chemotherapies, the expected impacts of the acquisition from NanoString on Veracyte, including its ability to expand its platform globally, its ability to increase the efficiency of its advanced genomic testing, and its plans to transfer its current and pipeline genomic tests onto the nCounter system; Veracyte's ability to advance the development and commercialization of novel diagnostic tests under the collaboration with Johnson & Johnson; the ability of Veracyte to achieve the expected benefits from the Acerta collaboration; and its ability to potentially inform diagnosis and treatment decisions in new oncology indications. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: Veracyte's ability to achieve and maintain Medicare coverage for its tests; the benefits of our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to Veracyte's business, including potential regulation by the Food and Drug Administration or other regulatory bodies; Veracyte's ability to successfully achieve and maintain adoption of and reimbursement for its products; the amount by which use of Veracyte's products are able to reduce invasive procedures and misdiagnosis, and reduce healthcare costs; the occurrence and outcomes of clinical studies; and other risks set forth in Veracyte's filings with the Securities and Exchange Commission, including the risks set forth in its annual report on Form 10-K for the year ended December 31, 2019. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

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