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Veracyte Announces Further European Reimbursement Expansion for Prosigna Breast Cancer Test

Only Test of Its Kind to Be Recommended for Use in All Swedish Healthcare Regions Without Restrictions

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 24, 2021-- Veracyte, Inc. (Nasdaq: VCYT) today announced that the Swedish Medical Technologies Product (MTP) Council has recommended the Prosigna Breast Cancer Assay for immediate reimbursement and clinical use in all Swedish healthcare regions without legal restrictions beginning November 22, 2021. The milestone follows recent G-BA reimbursement approval in Germany and underscores the test's continued reimbursement momentum in the European Union.

The recommendation from the Swedish MTP Council's first-ever process of its kind specifies that physicians can use the Prosigna assay to help make decisions about adjuvant chemotherapy in individual women over the age of 50 with certain types of breast cancer when there is uncertainty about the benefit of this treatment. It is based on a prior positive assessment from the Swedish Dental and Pharmaceutical Benefits Agency (Tandvårds Läkemedelförmånsverketthe, TLV), which conducted a health technology assessment (HTA) and concluded that the Prosigna test is a cost-effective genomic diagnostic technology for breast cancer.

The Prosigna assay is the only breast cancer genomic test that is both CE-IVD marked and recommended by the MTP Council without legal caveats regarding either General Data Protection Regulation (GDPR) compliance or adherence to processing of personal data requirements in Sweden and the European Union. The Prosigna test is performed locally by laboratories in Sweden and other countries on the nCounter Analysis System instrument.

"The positive TLV and MTP recommendations represent an important milestone for women with breast cancer throughout Sweden, because it makes it possible for them and their physicians to access the Prosigna test without restrictions to inform individual treatment decisions," said Morten Frost, Veracyte's general manager, Pulmonology and Breast Cancer. "The Swedish HTA is internationally recognized as a robust assessment with strict evidence and cost-effective requirements. We believe this recommendation reflects the robust evidence supporting the Prosigna assay, and we are actively working to make the test available to physicians and breast cancer patients who could benefit from it in other European countries."

The incidence of breast cancer is continuing to climb globally.[i] According to a report published by the Swedish National Board of Health & Welfare[ii], breast cancer is the most common cancer diagnosis for Swedish women, with up to about 10,000 new cases every year. In September 2020, the Swedish MTP Council decided to begin evaluating genomic diagnostics for breast cancer as part of the country's Orderly introduction framework, which aims to manage the national introduction of novel technologies.

"Clinical research and experience have demonstrated that understanding the gene expression profile of each patient's breast cancer is critical to selecting the most appropriate, individual treatment," said Johan Hartman MD, Ph.D., professor of Pathology, Karolinska Institutet, Stockholm, Sweden. "By making it possible for physicians in Sweden to access this detailed genomic information through regulatory approved diagnostic technologies such as the Prosigna test, the MTP and TLV recommendation could help improve care and outcomes for women across the country."

The Prosigna test is included in the European medical guidelines for the diagnosis and treatment of breast cancer. In addition to the Swedish MTP Council, UK NICE diagnostics guidance (DG34) and G-BA in Germany have recommended the test, which is also reimbursed in Spain, Denmark, Switzerland, and Israel.

"We are delighted that the Swedish MTP Council's recommendation will help ensure that the Prosigna test is accessible to women in Sweden with breast cancer," said Marc Stapley, Veracyte's chief executive officer. "Further, this latest milestone supports our strategic approach of offering our advanced genomic tests, beginning with Prosigna, in Europe and other countries on the nCounter Analysis System, which enables laboratories to run them for physicians and their patients locally. We believe this approach aligns well with the European regulatory environment and can improve patient outcomes by providing important clinical information more effectively and efficiently versus having to send patient samples back to the United States."

About The Prosigna Breast Cancer Assay

The Prosigna Breast Cancer Assay is a prognostic genomic test, built from PAM50 molecular subtypes, which combines tumor gene expression with clinicopathologic factors to better inform treatment decisions. The assay is indicated in female breast cancer patients who have undergone either mastectomy or breast-conserving therapy in conjunction with locoregional treatment consistent with standard of care, either as 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, or 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 Prosigna Breast Cancer Assay also provides the intrinsic subtypes of the tumor tissue within three groups – low, intermediate and high.* The test is performed on the nCounter Analysis System, enabling hospitals and laboratories to run it locally.

The Prosigna test has received the CE-IVD mark and is available for use by healthcare professionals in the European Union and other countries that recognize the CE-IVD mark, as well as in Canada, Israel, Australia, New Zealand and Hong Kong. The Prosigna test is FDA 510(k) cleared in the United States for use on the nCounter Analysis System and is available for use when ordered by a physician. The assay is widely covered by government and private payers in the countries where it is available, including by Medicare and leading private payers in the United States.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of diagnostic tests leverages advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer, colon cancer, and idiopathic pulmonary fibrosis are

available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic tests to patients worldwide. 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, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the Prosigna Breast Cancer Assay. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding our ability to secure reimbursement for the Prosigna Breast Cancer Assay in additional European countries. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, 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.

** Not available in the United States*

[i] Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. https://acsjournals.onlinelibrary.wiley.com/doi/pdf/10.3322/caac.21660

[ii] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2020-12-7132.pdf

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