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Prosigna Breast Cancer Assay Now Approved for Reimbursement in Germany

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 5, 2020-- Veracyte, Inc. (Nasdaq: VCYT), a pioneering genomic diagnostics company, announced that the Federal Joint Committee (G-BA) has approved its Prosigna® Breast Cancer Gene Signature Assay. The G-BA decision to reimburse the Prosigna test will provide access to the test for all breast cancer patients in Germany with HR+/HER2- early-stage breast cancer.

The Prosigna Assay is a second-generation breast cancer test, meaning that it uses advanced genomic technology combined with clinical and pathologic features to inform next steps for patients with early-stage breast cancer. The test analyzes the activity of 50 genes known as the PAM50 gene signature, along with tumor size, lymph node involvement, and a tumor proliferation score to provide early-stage breast cancer patients and their physicians with a prognostic score indicating the probability of cancer recurrence during the next 10 years.

“We are pleased with the G-BA decision, which will enable more breast cancer patients and their physicians in Germany to benefit from the genomic insights offered by our Prosigna test,” said Bonnie Anderson, chairman and chief executive officer of Veracyte. “Further, because Prosigna is performed by laboratories locally, this decision will enable German laboratories to deliver precision medicine solutions directly to their physician customers.”

The Prosigna test is recommended in guidelines from the German Association of Gynecologic Oncology (AGO), as well as the European Society for Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO) and the National Institute for Health and Care Excellence (NICE) in the United Kingdom.

Every year around 70,000 women in Germany develop early breast cancer. In many cases, a clear therapy recommendation for or against adjuvant chemotherapy is challenging based on the clinicopathological criteria alone. The Federal Joint Committee supports the use of biomarkers, now including Prosigna, to inform treatment decisions based upon the patient’s individual cancer recurrence risk.

About Prosigna

Prosigna is a prognostic Breast Cancer Gene Signature assay 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.

In addition to the risk of recurrence (ROR) information, in Europe the assay provides the intrinsic subtypes of the tumor tissue within three groups – low, intermediate and high. The test’s performance is validated for use on the nCounter Analysis System in laboratories across Europe.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic 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 genomic tests leverage 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 thyroid cancer, lung cancer, breast cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping test is in development. With Veracyte’s exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its tests to patients worldwide. 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 Veracyte’s Prosigna ® Breast Cancer Gene Signature Assay for use in predicting long-term risk of recurrence among breast cancer patients. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" 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 Veracyte’s belief that its Prosigna ® Breast Cancer Gene Signature Assay helps physicians accurately predict long-term risk of recurrence among breast cancer patients. 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 reimbursement coverage for its tests; the continued inclusion of its tests in recommendations of medical associations and agencies; the benefits of Veracyte’s tests and the applicability of clinical results to actual outcomes. Factors that may impact these forward-looking statements can be found in Item 1A – “Risk Factors” in our Annual Report on Form 10-K filed with the SEC on February 25, 2020 and in our Quarterly Report on Form 10-Q filed with the SEC on November 2, 2020. 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 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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