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Veracyte Announces ISO 13485:2016 Certification for Its In Vitro Diagnostics Quality Management System

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 21, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced that the company has received ISO 13485:2016 certification for its Quality Management System (QMS) for the design, development and manufacture of genomic *in vitro* diagnostic (IVD) tests that aid in the diagnosis and prognosis of cancer and other diseases. The achievement is a key milestone in the company's transformation into a global diagnostics provider following its December 2019 acquisition of the exclusive global diagnostics rights to the nCounter Analysis System, along with the Prosigna Prognostic Breast Cancer Gene Signature Assay that is performed on it.

ISO 13485:2016 is an internationally recognized quality standard specific to the medical device industry that is intended to ensure the quality of medical device design, development and production. To receive certification, organizations must demonstrate that their Quality Management Systems deliver medical devices and related services that consistently meet customer and regulatory requirements. ISO 13485 certification underscores the quality of the practices and processes used by Veracyte to develop tests on the nCounter system, and establishes the company as an IVD provider.

"I'm incredibly proud of our team for successfully completing the rigorous process to receive ISO 13485 certification for our IVD diagnostic processes just one year after we acquired rights to the nCounter system," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "This milestone demonstrates Veracyte's commitment to developing genomic tests for use on the nCounter system that comply with the highest standards of quality. Additionally, ISO 13485 certification will support our menu-expansion efforts on the nCounter system, including the planned introduction next year of our Envisia test in global markets and of our Lymphmark test, which currently is under FDA De Novo classification review."

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 for 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. 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 and expectations (financial and otherwise). 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. 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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