Veracyte Announces De Novo Classification Request to FDA for the nCounter Dx LymphMark Assay

June 9, 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 9, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced its submission of a De Novo classification request to the U.S. Food & Drug Administration (FDA) for the nCounter® Dx LymphMark ™ Assay, a novel, genomic lymphoma subtyping test. The *in vitro* diagnostic test is used on the nCounter Flex Analysis System, Veracyte's diagnostics platform, and is intended to add to Veracyte's portfolio of tests that address complex clinical problems, helping to inform diagnoses and better treatment decisions.

Veracyte has proposed the LymphMark test as an aid in disease characterization and prognosis to support disease management for patients newly diagnosed with diffuse large B-cell lymphoma (DLBCL). The LymphMark test utilizes gene-expression profiling of RNA extracted from formalin-fixed paraffin-embedded tissue to classify the "cell of origin" subtype of DLBCL tumors. The World Health Organization recommends gene-expression profiling for patients with DLBCL, given that certain subtypes are associated with poorer clinical outcomes, which may potentially be mitigated by more-specific treatments that are under development.[1]

"This submission marks an important milestone for Veracyte in our efforts to expand the menu of advanced genomic tests we provide on the nCounter system. Ultimately, our goal is to make our broader menu of tests accessible to patients worldwide through hospitals and laboratories that can perform them locally," said Bonnie Anderson, Veracyte's chairman and chief executive officer.

Veracyte acquired the LymphMark test in December 2019 as part of its acquisition from NanoString of the exclusive global diagnostic rights to the nCounter system.

"DLBCL is an aggressive form of lymphoma with heterogeneous clinical behavior – outcomes significantly depend upon the distinct molecular subtype of each patient's tumor," said Dr. David Scott, associate professor in the Department of Medicine at the University of British Columbia and a scientist in the Department of Lymphoid Cancer Research at BC Cancer, a program of the Provincial Health Services Authority. "The ability to determine this information from gene-expression profiling of tissue samples collected routinely in a clinical setting has the potential to transform patient care, making personalized treatment options more accessible."

Non-Hodgkin lymphoma ranks among the top-10 common cancers worldwide, with over 500,000 new cases estimated in 2018.[2] DLBCL accounts for approximately 30 percent of lymphomas.[3]

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. 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 LymphMark test to aid in disease characterization and prognosis to support disease management for patients newly diagnosed with DLBCL, the ability of Veracyte to expand the menu of advanced genomic tests on the nCounter system and the potential for gene-expression profiling of tissue samples to transform patient care. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: the impact of COVID-19 on Veracyte's business and operating results, specifically, and the healthcare system and economy more generally, 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-Q for the quarter ended March 31, 2020. 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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[1] Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revisions of the World Health Organization classification of lymphoid neoplasms. *Blood*. 2016;127(20):2375-2390.

[2] Miranda-Filho A, Piñeros M, Znaor A, Marcos-Gragera R, Steliarova-Foucher E, Bray F. Global patterns and trends in the incidence of non-Hodgkin lymphoma. *Cancer Causes Control*. 2019;30(5):489-499. doi:10.1007/s10552-019-01155-5.

[3] Types of B-cell Lymphoma. American Cancer Society. https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html. Accessed June 1, 2020.

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