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New Data Presented at ATS 2023 Reinforce Clinical Utility of Veracyte's Genomic Tests in Interstitial Lung Disease and Lung Cancer

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 24, 2023-- Veracyte, Inc. (Nasdaq: VCYT) today announced new data suggesting its novel genomic tests may positively impact diagnosis and care for patients being evaluated for interstitial lung disease (ILD) or lung cancer. The findings were presented at ATS 2023, the annual meeting of the American Thoracic Society, which is being held May 21-24 in Washington, D.C.

Findings from two posters suggest that the Envisia Genomic Classifier helps improve diagnosis and changes treatment decisions for patients with ILD. In an independent, real-world, multi-center study, researchers evaluated data for 98 patients with ILD for whom traditional high-resolution computed tomography (HRCT) and clinical factors alone failed to provide a clear diagnosis of ILD type. The Envisia test identified 42 patients with usual interstitial pneumonia (UIP), a lung-scarring pattern that is a hallmark of idiopathic pulmonary fibrosis (IPF), one of the most serious types of ILD. UIP is also associated with progressive disease that is not IPF. The test also identified 56 patients without UIP.

An Envisia-positive result for UIP prompted an increase in use of anti-fibrotic drugs (from 11.9% to 71.4%), which are used to treat IPF and other progressive ILDs. An Envisia-positive result for UIP also led to a reduction in immuno-suppressant drugs (from 23.8% to 9.5%), which can be harmful to patients with IPF.

"IPF and other progressive forms of ILD are often challenging to diagnose using traditional methods. Yet, accurate diagnosis is key to ensuring that patients receive timely and appropriate treatment," said Fayez Kheir, M.D., a pulmonologist at Massachusetts General Hospital in Boston and an author of the study. "Our findings suggest that use of the Envisia test helped physicians arrive at a more precise diagnosis and begin treatment with appropriate therapy sooner."

Findings from the second Envisia study suggest the genomic test can help identify whether the final diagnosis is IPF or another progressive fibrotic disease. In the study of 135 patients with undiagnosed ILD, researchers found that those with an Envisia-positive result for UIP had a lower baseline lung function, as measured by median forced vital capacity (FVC) testing results, compared to patients with an Envisia-negative result for UIP (64% vs. 75%). Patients with Envisia-positive results also had a greater absolute decline over one year (3% decline vs. 1% increase, p=0.03). The Envisia-positive group also had similar absolute declines in FVC over one year, regardless of whether they were diagnosed with IPF or another type of ILD (2.5% vs. 3%).

"These findings suggest that the Genomic Classifier may help identify patients who may progress and potentially prompt treatment interventions to decrease rate of progression," said Ganesh Raghu, M.D., director of the Center for Interstitial Lung Diseases at the University of Washington Medical Center.

For Veracyte's Percepta Nasal Swab, researchers presented updated preliminary study findings showing the test's potential to better stratify the risk of lung cancer for patients with lung nodules. The novel test is designed to help physicians more accurately, quickly and confidently assess cancer risk in lung nodules found on CT scans. Armed with this and other information, physicians may recommend that the nodule simply be monitored with imaging or may direct the patient to more-invasive diagnostic procedures or treatment.

The data continued to show that the Percepta Nasal Swab may classify more lung nodule patients as either low-risk or high-risk for lung cancer, as compared to the standard-of-care approach, which consists of a physician's own assessment of clinical factors or use of risk calculators, along with CT imaging. This additional clarity could potentially help more patients with benign nodules avoid unnecessary procedures, while ensuring that those patients at higher risk of cancer receive a diagnosis and treatment more quickly.

Previous data have demonstrated that the Percepta Nasal Swab test is highly accurate when it identifies patients as low-risk or high-risk for lung cancer. The test is available to a limited number of institutions as part of NIGHTINGALE, a multi-center, prospective trial that is underway to demonstrate its clinical utility.

"The data presented at ATS 2023 underscore Veracyte's commitment to delivering novel tests that help physicians make better diagnosis and treatment decisions for their patients being evaluated for serious lung diseases," said Bill Bulman, M.D., Veracyte's medical director, Pulmonology. "Importantly, these findings suggest that our tests in interstitial lung disease and lung cancer are performing as intended."

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally. 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 our clinical tests in and outside of the United States. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. An example of forward-looking statements include, among others, that use of the Envisia test can help physicians arrive at a more precise diagnosis and begin treatment with appropriate therapy sooner; the Genomic Classifier may help identify patients who may progress

and potentially prompt treatment interventions to decrease rate of progression; and Percepta Nasal Swab may classify more lung nodule patients as either low-risk or high-risk for lung cancer, as compared to the standard-of-care approach. 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 on February 22, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended March 30, 2023. Copies of these documents, when available, may be found in the Investors section of our website at investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim 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.

Veracyte delivers Envisia Genomic Classifier and Percepta Nasal Swab from its CLIA laboratories. Those tests are not CE-IVD marked and have not been cleared or approved by the FDA; their performance characteristics were determined by Veracyte. Please contact Veracyte for confirmation.

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