New Data Presented at CHEST 2023 Demonstrate the Clinical Utility of Veracyte's Envisia Genomic Classifier for Patients with Interstitial Lung Disease

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Two studies highlight the value of adding Envisia results to standard-of-care procedures for identifying patients at increased risk of progressive disease

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 12, 2023-- Veracyte, Inc. (Nasdaq: VCYT) today announced that new data presented at the American College of Chest Physicians (CHEST) Annual Meeting 2023 demonstrate the clinical utility of the company's Envisia Genomic Classifier, which is used by physicians to improve diagnostic and prognostic confidence of interstitial lung diseases (ILDs). The studies also underscore the challenge of identifying usual interstitial pneumonia (UIP) in patients being evaluated for ILD.

ILD is a broad group of disorders that lead to fibrosis, or scarring, of the lungs. People with ILD may find it difficult to breathe, and their condition often worsens over time. Among patients who have ILD, it is essential to identify those with UIP, which is a hallmark of idiopathic pulmonary fibrosis and is also associated with ILDs that are more likely to progress over time. Knowing that UIP is present may help a physician make more-informed treatment recommendations for their patients with ILD. However, UIP can be difficult to diagnose because it is challenging to detect using the standard approach of high-resolution computerized tomography (HRCT) and pathology-based diagnoses from a procedure such as cryobiopsy.

The studies presented at the CHEST Annual Meeting show that adding the Envisia Genomic Classifier to the diagnostic process can improve the ability to detect UIP.

In an independent study, researchers at UCLA Health evaluated electronic medical records for 83 patients to determine whether adding the Envisia Genomic Classifier to transbronchial lung cryobiopsy (TBLC) testing altered the diagnostic yield for UIP. Using just TBLC, a clear diagnosis could be made for only 46% of patients. That rate was even lower for patients with indeterminate HRCT results (23%). Adding results from the Envisia Genomic Classifier improved the diagnostic yield in both cases. Overall, combining the cryobiopsy procedure with the genomic classifier allowed for a diagnosis in 61% of cases. For patients with indeterminate HRCT results, adding the Envisia Genomic Classifier more than doubled the UIP diagnostic yield to 49%.

"We found that incorporating Envisia testing significantly increased the diagnostic yield of cryobiopsy for ILD in our overall cohort, as well as in the patients with indeterminate results on high-resolution CT," said Augustine Chung, M.D., pulmonary director of the Connective Tissue Disease-Interstitial Lung Disease Clinic at UCLA Health and an author of the study. "A higher diagnostic yield could help physicians recommend the most appropriate treatment for their patients with ILD."

The second study focused on the potentially subjective nature of results found on HRCT that was performed on patients with suspected ILD. Two expert thoracic radiologists independently reviewed and interpreted tomography scans for 74 cases of ILD, using the criteria recommended by current guidelines to look for the presence of UIP. Their conclusions were then compared to better understand variability between readers. The analysis showed that results were concordant in just 61% of cases, indicating that CT results may be less reliable than expected when used without a complementary test such as the Envisia Genomic Classifier. The lack of agreement was especially pronounced among cases that did not meet criteria for "typical" UIP, with concordance on "Probable UIP" seen in only 50% of cases and concordance on "Indeterminate for UIP" seen in 0% of cases.

"Collectively, these studies underscore the clinical value of the Envisia Genomic Classifier test for helping physicians determine whether UIP is present in patients with ILD," said Bill Bulman, M.D., Veracyte's medical director for Pulmonology. "They also support the clinical utility of using the Envisia test as a complement to current diagnostic procedures to improve ILD diagnostic and prognostic confidence."

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. Examples of forward-looking statements include, among others, that adding the Envisia Genomic Classifier to current diagnostic procedures will enable more reliable and complete results. 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 March 1, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended June 30, 2023. Copies of these documents, when available, may be found in the Investors section of our website at https://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.

Envisia GC is available in the US as part of Veracyte's CLIA-validated laboratory developed test (LDT) service. This test has not been cleared or approved by the FDA.

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