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Veracyte Announces Clinical Utility Study Published in CHEST Demonstrates Envisia Genomic Classifier's Ability to Improve IPF Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 11, 2020-- Veracyte, Inc. (Nasdaq: VCYT) announced today the publication of an independent study showing that the Envisia Genomic Classifier enables physicians to more confidently diagnose idiopathic pulmonary fibrosis (IPF), a progressive lung disease, when results from high-resolution CT (HRCT) imaging are not definitive. The real-world clinical findings appear online ahead of print in _CHEST_, the journal of the American College of Chest Physicians.

The Envisia classifier is the first and only commercially available genomic test that helps distinguish IPF from other interstitial lung diseases (ILDs), without the need for risky surgery. Veracyte developed the classifier by combining RNA whole-transcriptome sequencing and machine learning, which enables a comprehensive genomic approach for distinguishing the usual interstitial pneumonia (UIP) pattern, whose presence is essential to IPF diagnosis. Veracyte is preparing to launch the test in global markets in 2021.

The new study compared the impact of Envisia classifier results on diagnostic decision-making among two physician multidisciplinary discussion (MDD) groups that each evaluated 24 patients with suspected IPF or other ILDs whose HRCT results were inconclusive. The groups sequentially reviewed clinical and HRCT findings, followed by Envisia results, either after (MDD1) or before (MDD2) findings from cryobiopsy (a diagnostic procedure that is sometimes conducted during bronchoscopy). In each case, the MDD group sought additional information, including UIP, to make a more confident ILD diagnosis, including IPF in some cases.

The researchers found that the rate of high-confidence diagnosis was significantly higher for the MDD1 group after adding the Envisia results to those of cryobiopsy (46% to 75%). The increase in a confident diagnosis was higher for those individuals with "probable" UIP (43% to 93%) and patients with a final diagnosis of IPF (31% to 92%). Additionally, they found high overall agreement between the Envisia result and the final diagnosis of UIP or non-UIP for both MDD groups (96% and 92%, for MDD1 and MDD2 respectively) as compared to 83% agreement between cryobiopsy results and both MDD groups.

"Distinguishing IPF from other ILDs can be challenging even in settings where a multidisciplinary approach is used. However, obtaining a timely, accurate diagnosis is critical to rapidly initiate and optimize treatments to slow disease progression," said Joseph Lasky, M.D., professor of medicine at Tulane University and corresponding author of the study. "Our findings suggest that integrating Envisia classifier genomic data into the full context of recommended practice enables clinicians to increase their confidence in diagnosing IPF, particularly in patients whose imaging results suggest probable UIP, but for whom a secure diagnosis remains in doubt."

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected ILDs, including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. A survey conducted by the Pulmonary Fibrosis Foundation showed that 55 percent of IPF/ILD patients are misdiagnosed at least once and, for one in five patients, accurate diagnosis took three or more years. Accurate and timely diagnosis is important because therapies are now available to slow the progression of IPF.

"This new publication adds to the growing body of clinical evidence showing that the Envisia classifier helps physicians make a more confident diagnosis of IPF," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "We believe our test can significantly improve care for patients with suspected IPF, helping them avoid unnecessary surgeries and receive appropriate treatment more quickly. These findings are important to helping us expand coverage with commercial payers, pursue clinical guideline inclusion and expand access for the Envisia classifier globally."

About Envisia

The Envisia Genomic Classifier is the first commercially available test to improve the diagnosis of idiopathic pulmonary fibrosis (IPF). The genomic test enables physicians to more confidently differentiate IPF from other interstitial lung diseases (ILDs), helping to guide an optimal patient treatment plan that can improve outcomes and reduce risk. The Envisia classifier was developed using RNA whole-transcriptome sequencing and machine learning to identify the usual interstitial pneumonia (UIP) pattern, which is a hallmark of IPF. The test assesses patient samples obtained through bronchoscopy, a nonsurgical procedure commonly used in lung evaluation, and is used as a complement to high-resolution computed tomography (HRCT). The Envisia classifier is proven to detect UIP with high correlation to the gold standard – histopathology results read by ILD experts – without the need for surgery.

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 the Envisia classifier's ability to diagnose IPF. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and

assumptions. 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 Veracyte's 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 quarterly 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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