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Veracyte Announces Publication of Data Demonstrating Clinical Utility of Its Envisia Genomic Classifier to Improve IPF Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 14, 2021-- Veracyte, Inc. (Nasdaq: VCYT) announced today the publication of clinical utility data confirming the ability of the Envisia Genomic Classifier to improve diagnostic and treatment decision-making for patients with idiopathic pulmonary fibrosis (IPF). The findings, which appear online in the *Annals of the American Thoracic Society* (*AnnalsATS*), suggest that use of the test increases diagnostic accuracy, physician confidence in diagnosis, and patient referral to appropriate therapy, while also reducing invasive and potentially risky surgical lung biopsies (SLBs). Findings from the study were previously presented at the CHEST Annual Meeting 2021 in October.

Veracyte estimates that each year in the United States and Europe approximately 200,000 patients have unclear results following evaluation for suspected interstitial lung diseases (ILDs), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. The Envisia classifier is a highly accurate, clinically validated molecular test that detects a genomic pattern of usual interstitial pneumonia (UIP), a critical factor that can help physicians differentiate IPF from other ILDs.

“IPF and other ILDs are often challenging to diagnose, yet a correct and timely diagnosis is a critical first step to support more effective treatment for patients,” said Joseph Lasky, M.D., professor and Pulmonary/Critical Care Section Chief at Tulane University School of Medicine and lead author of the paper. “Our findings demonstrate the clinical utility of the Envisia classifier by increasing the number of IPF diagnoses and associated confidence in those diagnoses, while avoiding more-invasive procedures. Importantly, use of the genomic test in the diagnostic work-up also led to increased recommendation for antifibrotic therapies, which have been shown to improve outcomes of patients with IPF.”

For the study, each survey participant received five patient cases from the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) study and was asked to determine an ILD diagnosis, their confidence level in their diagnosis and the next management step. A cohort of 81 physicians initially reviewed cases without Envisia test results (pre-Envisia) and then again with the classifier results added (post-Envisia). Researchers randomly selected the patient cases from a set of 11 that all had undiagnosed ILD, a high-resolution computed tomography (HRCT) scan without a “typical” UIP pattern, and a UIP-positive Envisia test result, and had undergone multidisciplinary team discussion that resulted in a final diagnosis of IPF. Among the cohort of 81 physicians who reviewed cases both pre- and post-Envisia (a total of 155 case reviews), use of the Envisia test:

- Increased IPF diagnosis by an absolute difference of 39%, from 47 (30%) pre-Envisia to 107 (69%) post-Envisia, and also decreased the number of unclassifiable ILD diagnoses by an absolute difference of 10.5%, from 24 (15%) to 7 (4.5%)
- Increased the number of physicians saying they had a high level of confidence (≥90%) in their diagnosis by an absolute difference of 36.2%, from 9 (5.8%) pre-Envisia to 65 (42%) post-Envisia
- Increased the recommendation for patients to initiate antifibrotic treatment by an absolute difference of 36.4%, from 15 (10%) pre-Envisia to 72 (46.4%) post-Envisia
- Decreased the recommendation for an SLB or cryobiopsy significantly decreased from 40 (26%) pre- Envisia to 26 (17%) post-Envisia

“Patients often undergo a frustrating diagnostic odyssey to obtain a diagnosis of IPF or another ILD,” said William T. Schmidt, president and chief executive officer of the Pulmonary Fibrosis Foundation. “In fact, our prior research showed that more than half of patients reported being misdiagnosed at least once and 43% reported waiting at least a year from when they first experienced symptoms to when they received a correct diagnosis. These findings underscore the role that advanced technology, such as the Envisia classifier, can potentially play in helping patients obtain the diagnosis and treatment they need.”

“We developed the Envisia Genomic Classifier to help physicians make more timely and accurate diagnosis and treatment recommendations for their ILD patients,” said Marc Stapley, Veracyte’s chief executive officer. “This publication underscores the test’s ability to achieve these objectives and ultimately improve care for patients.”

About Veracyte

Veracyte (Nasdaq: VCYT) is a global 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 diagnostic tests leverages 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 lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte’s exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic 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, expectations (financial and otherwise) or intentions with respect to the Envisia Genomic Classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," “suggest,” "may," "will" “prospective” and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte’s belief that its Envisia Genomic Classifier can significantly improve the diagnosis of ILDs, including IPF, and assist healthcare providers in selecting patient treatment options. 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 with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. 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, except as required by law, 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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