Veracyte Announces Presentation of Data Confirming Envisia Genomic Classifier's Ability to Improve Diagnosis of Idiopathic Pulmonary Fibrosis

October 8, 2018

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 8, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced the presentation of data demonstrating that the Envisia Genomic Classifier can help physicians more confidently diagnose interstitial lung disease (ILD), including idiopathic pulmonary fibrosis (IPF), without the need for surgery. The data were shared today in an oral presentation at CHEST 2018, the annual meeting of the American College of Chest Physicians®, which is being held October 6-10 in San Antonio, Texas.

Using data from a prospective study of 49 patients presenting with new-onset ILD, researchers evaluated samples obtained through nonsurgical transbronchial biopsy to determine the Envisia classifier's accuracy in detecting usual interstitial pneumonia (UIP), a pattern whose presence is essential to IPF diagnosis. Utilizing histopathology as the reference standard, investigators found that the genomic test shows a specificity of 88 percent and sensitivity of 70 percent for detecting UIP. While high-resolution computed tomography (HRCT) is typically the first step in distinguishing IPF from other ILDs, previous data have shown that up to 50 percent of UIP cases are missed by HRCT alone. Among the 42 cases in the current study with the lowest diagnostic confidence following HRCT – i.e., those without definite or probable UIP – the Envisia classifier provided even more robust results (88 percent specificity and 76 percent sensitivity).

"An accurate, timely diagnosis of IPF and other ILDs is a major challenge for physicians and patients, but is essential for optimal treatment," said David Lynch, MB, BCh, Professor of Radiology at National Jewish Health, who presented the findings. "Our data, while based on relatively small numbers, suggest that the Envisia test can provide important information for diagnosis, as a complement to HRCT and clinical findings. This is particularly true among patients whose results are unclear following HRCT imaging."

"Recent study findings show that patients being evaluated for suspected IPF or other ILDs often endure significant diagnostic delays, misdiagnosis and invasive, costly procedures, which can negatively impact outcomes and increase risk," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "These new data reinforce the valuable role that the Envisia Genomic Classifier can play in improving IPF diagnosis. They also add to the growing body of evidence supporting the use of our test."

The Envisia classifier is currently available to a limited number of institutions through an Early Access Program. In August 2018, Veracyte received a draft Medicare coverage policy for the Envisia classifier through the MolDx program. The company expects the final policy will go into effect in early 2019 and plans to expand availability of the test in 2019.

About Interstitial Lung Disease

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected ILD, including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. Physicians routinely use HRCT along with a clinical work-up to help identify IPF, but this approach frequently provides inconclusive results, leading many patients to undergo invasive and potentially risky surgery for a more definitive diagnosis. Other patients are too frail to undergo surgery and may never receive an accurate diagnosis, which can result in suboptimal - and potentially harmful - treatment.

About Envisia

The Envisia Genomic Classifier is the first commercially available test to improve the diagnosis of idiopathic pulmonary fibrosis (IPF). The Envisia test enables physicians to more confidently differentiate IPF from other interstitial lung diseases (ILD), helping to guide an optimal patient treatment plan that can improve outcomes and reduce risk. The classifier works by harnessing the power of RNA sequencing and machine learning to detect a genomic pattern of usual interstitial pneumonia (UIP), whose presence is required for IPF diagnosis. The Envisia test 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 leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company's products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. 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, our belief that our genomic tests will transform the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis; statements regarding the ability of the Envisia Genomic Classifier to reduce the need for invasive procedures in and improve IPF diagnosis; and statements regarding the draft and any final Medicare coverage policy for the Envisia Genomic Classifier. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our ability to achieve Medicare coverage for our tests, the market opportunity for the Envisia classifier, the benefits of our tests, the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to sell our Afirma tests and successfully transition to our next-generation Afirma GSC; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our 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 our filings with

the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 2018. 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, except as required by law.

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