April 1, 2019

Veracyte Announces Data Published in The Lancet Respiratory Medicine Demonstrate that the Envisia Genomic Classifier Improves Diagnosis of IPF

Novel genomic test distinguishes IPF from other lung-scarring diseases without the need for surgery

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 1, 2019-- Veracyte, Inc. announced that data published online today in *The Lancet Respiratory Medicine* suggest that use of the company's Envisia Genomic Classifier improves diagnosis for patients undergoing evaluation for interstitial lung diseases (ILDs), including idiopathic pulmonary fibrosis (IPF). The Envisia classifier is the first commercially available test that may help distinguish IPF from other ILDs, without the need for risky surgery. The Envisia classifier recently received Medicare coverage, making it the first test of its kind for improving IPF diagnosis to be covered for the nation's 55 million Medicare patients.

Over 100,000 people in the United States have lung-scarring ILDs, including IPF, which is the deadliest type, and the number is rising. While therapies are now available to slow progression of this deadly disease, 55 percent of IPF/ILD patients reported being misdiagnosed at least once and, for one in five patients, accurate diagnosis took three or more years, according to a study by the Pulmonary Fibrosis Foundation.

"IPF is often challenging to distinguish from other ILDs, but timely and accurate diagnosis is critical so that patients with IPF can access therapies that may slow progression of the disease, while avoiding potentially harmful treatments," said Ganesh Raghu, M.D., Director, Center for Interstitial Lung Diseases, and Professor of Medicine at the University of Washington and lead author of the new paper. "Our results with molecular classification through machine learning (the Envisia classifier) are promising and, along with clinical information and radiological features in high-resolution CT imaging, physicians through multidisciplinary discussions, may be able to utilize the molecular classification as a diagnostic tool to make a more informed and confident diagnoses."

The new paper includes data from a clinical validation and a clinical utility study, both conducted using data from patients enrolled in the ongoing, prospective, 29-site, blinded BRAVE (Bronchial Sample Collection for a Novel Genomic Test) study. The clinical validation study assessed the Envisia classifier's ability to identify the usual interstitial pneumonia (UIP) pattern, whose presence is essential to IPF diagnosis. Among 49 patients who met the study criteria (and were not used to train the genomic classifier algorithm), the Envisia classifier achieved a specificity of 88 percent and sensitivity of 70 percent for UIP. These findings mean that the test would be expected to identify more than two-thirds of UIP cases with a high degree of accuracy, while minimizing the number of false positive results, providing physicians with greater confidence in their diagnosis. In comparison, data show that high-resolution CT (HRCT) imaging, which is typically used in IPF diagnosis, has a sensitivity of just 43 percent for UIP.

In the clinical utility study, known as CATALYST (Clinical Utility Analysis of a UIP Genomic Classifier in the BRAVE Trial), two multidisciplinary teams (MDTs) conducted blinded reviews of 94 study participants' medical charts. Researchers found that when the Envisia classifier was used as a complement to HRCT in an MDT evaluation, there was high agreement (86 percent) in IPF versus non-IPF diagnoses when evaluating the same patients with HRCT and surgical histopathology results. Further, when both MDTs made an IPF diagnosis, the authors observed that the MDT with Envisia classifier results was significantly more confident in its IPF diagnosis compared to the team with surgical histopathology results (89 percent versus 56 percent).

"These findings show that, when paired with HRCT results and patient clinical history, the Envisia classifier gave physicians a higher level of confidence in making an IPF diagnosis," said Sadia Benzaquen, M.D., director of interventional pulmonology at UC Health in Cincinnati, Ohio, and an author of the paper.

"The data published today underscore the performance and significant value that the Envisia Genomic Classifier brings to physicians, patients and the healthcare system," said Bonnie Anderson, chairman and chief executive officer of Veracyte. "We believe our test has the potential to transform the diagnosis of IPF and other ILDs. More immediately, this new paper, combined with the Medicare coverage policy for the Envisia classifier issued recently, will fuel our efforts to make the classifier more widely available to the patients across the country who can benefit from it."

About Interstitial Lung Disease

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected interstitial lung disease, including idiopathic pulmonary fibrosis, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. Physicians routinely use high-resolution computed tomography (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 genomic 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 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. In August 2018, the Centers for Medicaid & Medicare Services issued a draft Medicare coverage policy for the Envisia classifier and a final coverage decision is expected in early 2019.

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. 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 ability to achieve and maintain Medicare coverage for our tests, including the Envisia Genomic Classifier; the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, on the timing of the commercialization of the Percepta classifier, and on the size of Veracyte's addressable market. 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: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; the benefits of our tests and 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 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 annual report on Form 10-K for the year ended December 31, 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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