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Veracyte Announces New Clinical Utility Data Suggesting Envisia Genomic Classifier Enables as Confident a Diagnosis in IPF as Surgical Pathology

- Interim CATALYST Study Findings Presented at PFF Summit -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Veracyte, Inc.](#) (NASDAQ: VCYT) announced that new data for the Envisia™ Genomic Classifier were presented today and demonstrate that the test - in real-world clinical scenarios - can enable diagnosis of idiopathic pulmonary fibrosis (IPF) by a central multidisciplinary team (MDT), without the need for surgery. The findings are important because IPF is often challenging to distinguish from other interstitial lung diseases (ILDs) without invasive, costly and risky surgery. The new data were shared during the Pulmonary Fibrosis Foundation's biannual PFF Summit, being held November 9-11 in Nashville, Tenn.

In the interim report from the CATALYST clinical utility study, researchers found that two central MDTs - each comprised of a pulmonologist, radiologist and pathologist - diagnosed patients with suspected IPF similarly (92 percent agreement) when they were randomly assigned to review either the patients' surgical pathology or Envisia classifier results, along with clinical information and high-resolution computed tomography (HRCT). The study also showed that the Envisia classifier enabled the MDTs to agree on a diagnosis (94 percent agreement) based on Envisia classifier results, even when surgical pathology results were inconclusive. The findings are from a retrospective analysis involving 71 patients who were evaluated for potential IPF using HRCT, surgical pathology and genomic testing with the Envisia classifier.

"These findings signal a real potential for a shift in the current diagnostic evaluation of patients undergoing evaluation for ILD," said Neil M. Barth, M.D., chief medical officer of Veracyte. "Prior to the introduction of the Envisia classifier, clinicians and patients were limited to surgery for confirming a diagnosis of IPF, if the HRCT was inconclusive. Many patients are not willing or medically eligible to undergo such an invasive procedure. Envisia has now been shown to enable as confident a diagnosis in IPF as surgical pathology. This removes many of the previous barriers to achieving a timely and accurate diagnosis."

About Interstitial Lung Disease and Idiopathic Pulmonary Fibrosis

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 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 the Envisia Genomic Classifier

The Envisia Genomic Classifier is designed to improve physicians' ability to differentiate IPF from other ILDs without the need for surgery. The 190-gene classifier uses machine learning coupled with powerful, deep RNA sequencing to detect the presence or absence of usual interstitial pneumonia (UIP), a classic diagnostic pattern whose presence is essential for the diagnosis of IPF, using patient samples obtained through less-invasive transbronchial biopsy.

About Veracyte

Veracyte (NASDAQ: VCYT) is a leading genomic diagnostics company that is providing trustworthy and actionable answers that fundamentally improve patient care when current diagnostic tests are uncertain. The company's products uniquely combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward without risky, costly surgery that is 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 the preliminary findings signal a real potential for a shift in the current diagnostic evaluation of patients undergoing evaluation for ILD, our belief that use of our test may remove many of the previous barriers to achieving a timely and accurate diagnosis, and the applicability of clinical results to actual outcomes. 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: the final results of the CATALYST clinical utility study; demand for our tests; the applicability of clinical results to actual outcomes; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; the size of the market opportunity for our products; 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; the timing and publication of clinical study results; and other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

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