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Veracyte Announces Clinical Validation Data Demonstrating Envisia™ Genomic Classifier's Performance in Improving Idiopathic Pulmonary Fibrosis Diagnosis Presented at ATS 2017

SOUTH SAN FRANCISCO, Calif., May 23, 2017 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a genomic diagnostics company focused on reducing unnecessary surgeries and healthcare costs by resolving diagnostic uncertainty, announced today that pivotal clinical validation data demonstrating the performance of its Envisia Genomic Classifier were presented at the American Thoracic Society 2017 International Conference (ATS 2017) being held in Washington, DC. The genomic test is used to improve diagnosis of idiopathic pulmonary fibrosis (IPF), a common and severe form of interstitial lung disease (ILD), which is often challenging to diagnose without surgery.

At the ATS meeting today, investigators presented pivotal clinical validation study results confirming the Envisia classifier's ability to detect usual interstitial pneumonia (UIP), a pattern whose presence is essential to IPF diagnosis, without the need for surgery. The genomic test identified UIP vs. non-UIP with high specificity of nearly 90% and demonstrated sensitivity of 67 percent, meaning it would be expected to identify two thirds of UIP cases with a high degree of accuracy. This performance was compared to a reference standard of histopathology review by a central panel of pathologists with expertise in ILD. The findings are from the 30-site, prospective BRAVE trial and involved 236 transbronchial biopsy (TBB) samples from 49 patients.

"By providing information that today can often only be obtained through surgery, the Envisia classifier has the potential of enabling the diagnosis of IPF," said Ganesh Raghu, M.D., professor of medicine in the Division of Pulmonary and Critical Care Medicine and director of the Center for Interstitial Lung Disease at the University of Washington and senior author of the study. "This new molecular approach to diagnosis of IPF will hopefully serve the patients better in ascertaining the diagnosis of IPF."

Data were also presented from an analytical verification study demonstrating the Envisia classifier's strong accuracy, reproducibility, and robustness in distinguishing UIP from non-UIP under conditions that emulate the operational and biological variation that may be encountered in routine testing. The study included assessing the classifier's ability to determine gene expression in a pooled RNA sample composed of multiple (3-5) TBB samples per patient, with varying mixtures of each sample, illustrating that the test is robust across sampling variations.

"The data presented today demonstrate the significant role that the Envisia Genomic Classifier can play in resolving uncertainty in IPF diagnosis so that patients can get the answers they need without undergoing surgery," said Bonnie Anderson, Veracyte's chief executive officer and chairman. "These data also represent remarkable progress as we build the library of clinical evidence to support physician adoption and payer reimbursement for the test."

About Interstitial Lung Disease
Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected interstitial lung disease (ILD), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. Physicians routinely use high-resolution computed tomography (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, or UIP, a classic diagnostic pattern whose presence is essential for the diagnosis of IPF, using samples obtained through less-invasive bronchoscopy.

About Veracyte
Veracyte (NASDAQ: VCYT) is a leading genomic diagnostics company that is fundamentally improving patient care by resolving diagnostic uncertainty with evidence that is trustworthy and actionable. 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," "expected," "can," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, our estimate of the number of patients who have avoided unnecessary surgery, our beliefs regarding the potential benefits of our tests to patients, physicians and payers and our beliefs regarding the market opportunity for our products. 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: 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 March 31, 2017. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.