

Veracyte Announces Publication of Study Supporting the Development of Envisia™ Genomic Classifier for IPF in Annals of the American Thoracic Society

SOUTH SAN FRANCISCO, Calif., June 27, 2017 /PRNewswire/ -- <u>Veracyte, Inc.</u> (NASDAQ: VCYT) announced today that results of a study supporting the early development of the Envisia Genomic Classifier have been published online in the <u>Annals of the American Thoracic Society</u>. The genomic test, introduced commercially in October 2016, is used to improve the diagnosis of idiopathic pulmonary fibrosis (IPF), a common and severe form of interstitial lung disease (ILD), which is often challenging to diagnose without surgery.

In the study, the authors demonstrated that the initial genomic classifier could accurately identify those patients with a histologic pattern of usual interstitial pneumonia (UIP) without the need for surgery. The Envisia classifier was developed using machine learning and whole-genome RNA sequencing to identify the genomic signature of UIP, a pattern whose presence is essential to IPF diagnosis, from less-invasive transbronchial biopsies (TBB) which frequently are insufficient to yield a standard histopathology diagnosis. In the study published today, researchers evaluated 283 TBB samples from 84 patients who were enrolled in the prospective, multicenter BRAVE Study. They found the classifier had a specificity of 86 percent and sensitivity of 63 percent, suggesting it could identify nearly two-thirds of UIP cases with a high degree of accuracy. This performance was compared to a reference standard of paired surgical samples whose UIP/non-UIP histopathology pattern was conferred by a central panel of three pathologists with expertise in ILD.

"These strong early results informed the development of our commercialized Envisia Classifier, which we believe can help significant numbers of patients with suspected IPF obtain a more timely, accurate and safer diagnosis," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "These newly published findings also reinforce the scientific and clinical rigor that went into the Envisia Classifier's development. We believe that this foundational work, along with the robust clinical validation data we have shared in recent months, will build the body of published evidence needed to drive physician adoption and payer reimbursement of the Envisia Genomic Classifier test."

At the recent American Thoracic Society 2017 International conference, investigators presented results of the pivotal clinical validation study showing that the commercialized version of the Envisia Classifier detected even higher specificity and sensitivity than the early prototype classifier data published today.

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 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 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 beliefs regarding the potential benefits of our tests to patients, physicians and payers, our beliefs regarding the scientific and clinical rigor that went into the Envisia Classifier's development and our beliefs regarding our ability to build the body of published evidence needed to drive physician adoption and payer reimbursement for the test. 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.

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To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/veracyte-announces-publication-of-study-supporting-the-development-of-envisia-genomic-classifier-for-ipf-in-annals-of-the-american-thoracic-society-300480049.html</u>

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