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Veracyte Launches Early Access Program for Envisia Genomic Classifier to Improve Diagnosis of IPF

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 17, 2018-- [Veracyte, Inc.](#) (Nasdaq: VCYT) today announced that it has launched an Early Access Program to begin making the Envisia Genomic Classifier available to patients being evaluated for interstitial lung diseases (ILD), including idiopathic pulmonary fibrosis (IPF). Physicians from Jefferson (Philadelphia University + Thomas Jefferson University), Keck Medicine of USC, Providence Sacred Heart Medical Center in Washington state and University of California, Los Angeles (UCLA) are among the first to participate in the program, offering patients the new genomic test to enable more confident IPF diagnoses and help ensure optimal treatment – without the need for surgery.

"Obtaining an accurate, timely IPF diagnosis is important given the availability of new drugs that can slow the progression of this debilitating disease, as well as the need to avoid inappropriate and potentially harmful treatment," said S. Samuel Weigt, M.D., M.S., associate professor of medicine at UCLA and director of UCLA Health's Interstitial Lung Disease Center. "Unfortunately, IPF is often difficult to distinguish from other ILDs, even with the most advanced imaging technologies. Further, diagnostic surgery is risky, expensive and may not be viable for some patients. We are pleased to be one of the few medical facilities in the country to have access to this breakthrough technology."

A [recently published study](#) by the Pulmonary Fibrosis Foundation found that more than half of patients with IPF or other ILDs were misdiagnosed at least once and that, for four in 10 ILD patients, diagnosis took more than a year. Among those patients with IPF, more than one in five reported treatment during the diagnostic process with systemic corticosteroids, a potentially harmful therapy for IPF patients.

The Envisia Genomic Classifier combines RNA sequencing and machine learning to improve physicians' ability to differentiate IPF from other ILDs through patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation. The 190-gene test detects the genomic pattern of usual interstitial pneumonia (UIP), a hallmark of IPF, with high accuracy (88 percent specificity and 70 percent sensitivity).

"Multiple studies have demonstrated that the Envisia Genomic Classifier supports more confident IPF diagnosis and optimal patient management," said Bonnie Anderson, chairman and chief executive officer of Veracyte. "We are honored to be working with physicians at leading institutions as we begin making the test available to help ease what is often a challenging diagnostic journey for patients with IPF or other ILDs. Our Early Access Program – while limited to a small number of institutions – will enable us to begin providing access to the test in advance of its anticipated, nationwide commercial expansion in 2019."

For more information about accessing the Envisia Genomic Classifier through the Early Access Program, physicians and patients may contact Veracyte at 844-464-5864 or support@veracyte.com.

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) 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 Veracyte

Veracyte, Inc. (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 our genomic tests will transform the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis; statements regarding the anticipated offerings under the launch of our Early Access Program; and statements regarding the ability of the Envisia Genomic Classifier to improve IPF diagnosis. 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 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 March 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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