Veracyte Announces Expansion of Envisia Genomic Classifier Early Access Program

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20 Medical Centers Across the U.S. Now Offering First Test to Improve Diagnosis of Idiopathic Pulmonary Fibrosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 5, 2018-- Veracyte, Inc. (Nasdaq: VCYT) today announced that 20 medical centers across the United States are now offering the Envisia Genomic Classifier through an Early Access Program (EAP) to patients who are undergoing evaluation for interstitial lung diseases (ILD), including idiopathic pulmonary fibrosis (IPF). The program, launched in May 2018, provides advance access to the Envisia classifier, which the company anticipates making available nationwide in 2019. The Envisia Genomic Classifier was developed using the company's RNA whole-transcriptome sequencing and machine learning technology to improve physicians' ability to differentiate IPF from other ILDs – without the need for surgery.

Physicians from Banner – University Medical Center Tucson, Banner – University Medical Center Phoenix, Cleveland Clinic, Cooper University Health Care, Penn Highlands Healthcare, Tulane University School of Medicine and University Hospitals Cleveland Medical Center are among the most recent to participate in the Envisia EAP. They join Jefferson (Philadelphia University + Thomas Jefferson University), Keck Medicine of USC, Providence Sacred Heart Medical Center in Washington state and University of California, Los Angeles, and others whose participation was previously announced. Patients can now access the Envisia classifier in 12 states across the country.

"Accurate and timely diagnosis of IPF and other ILDs is often a major challenge for physicians and patients, even with the most advanced imaging technologies," said Joseph A. Lasky, M.D., of Tulane University School of Medicine. "A precise diagnosis is fundamental for developing an optimal patient treatment plan. This may include the use of antifibrotic therapies that are now available to slow progression of IPF, as well as the avoidance of potentially harmful treatments. We are delighted to be one of the first medical centers in the United States to offer this breakthrough genomic technology to our patients."

A recently published survey conducted 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, accurate 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.

"For many patients with IPF or other ILDs, the emotional toll of learning they have a serious lung disease is often compounded by the challenges they experienced in getting a diagnosis," said Sandeep Bansal, M.D., medical director for The Lung Center at Penn Highlands Healthcare, headquartered in DuBois, Pennsylvania. "Data suggest that the Envisia Genomic Classifier can help us reduce this burden and significantly improve care for these patients."

The 190-gene Envisia classifier detects the genomic pattern of usual interstitial pneumonia (UIP), a hallmark of IPF, with high accuracy (88 percent specificity and 70 percent sensitivity). The genomic test is performed on patient samples obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation. Veracyte recently received a draft Medicare local coverage decision through the MolDX program for its Envisia classifier and anticipates that the policy will become final in early 2019.

"As a complement to high-resolution CT imaging, the Envisia classifier can improve patient care by enabling physicians to more confidently differentiate IPF from other ILDs," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "This may help patients get appropriate treatment sooner, without the need for risky surgery or other diagnostic procedures. We are pleased to be working with physicians at leading hospitals through our Early Access Program as we prepare to make the Envisia classifier more widely available to patients 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 Envisia

The Envisia Genomic Classifier is the first commercially available test to improve the diagnosis of idiopathic pulmonary fibrosis (IPF). The Envisia classifier 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 classifier works by harnessing the power of RNA sequencing and machine learning to detect a genomic pattern of usual interstitial pneumonia (UIP), whose presence is required for IPF diagnosis. 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.

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 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 ability of the Envisia Genomic Classifier to reduce the need for invasive procedures in and improve IPF diagnosis, and its availability through the Early Access Program; and statements regarding the draft and any final Medicare coverage policy for the Envisia Genomic Classifier. 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: our ability to achieve Medicare coverage for our tests, the market opportunity for the Envisia classifier, 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 September 30, 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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