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Veracyte Receives Regulatory Authorization to Offer Envisia Genomic Classifier for Patients in New York State

Novel Genomic Test Helps Improve Diagnosis of Idiopathic Pulmonary Fibrosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 22, 2019-- Veracyte, Inc. (Nasdaq: VCYT), a leading genomic diagnostics company, announced today that it has received regulatory authorization from the New York State Department of Health to offer the Envisia™ Genomic Classifier for patients in the state effective immediately. The genomic test is the first commercially available test to help distinguish idiopathic pulmonary fibrosis (IPF) from other interstitial lung diseases (ILD), without the need for risky surgery.

"We are pleased that the Envisia classifier will now be available to physicians and their patients in New York State," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "This milestone, along with a recent Medicare coverage policy, underscores the strength of the clinical evidence behind the Envisia classifier and the critical need for better diagnosis among patients being evaluated for ILDs, including IPF."

Over 100,000 people in the United States have lung-scarring ILDs, including IPF, which is the deadliest type, and the number is rising. While therapies are now available to slow progression of this deadly disease, 55 percent of IPF/ILD patients reported being misdiagnosed at least once and, for one in five patients, accurate diagnosis took three or more years, according to a study by the Pulmonary Fibrosis Foundation.

Earlier this month, clinical validation and clinical utility data for the Envisia classifier were published in *The Lancet Respiratory Medicine*, demonstrating the test's ability to identify the telltale pattern of IPF, while minimizing false positive results, and its usefulness in giving physicians more confidence in their diagnosis of patients being evaluated for interstitial lung disease, including IPF, without the need for surgery.

The Envisia classifier is used as a complement to high-resolution computed tomography (HRCT).

About Interstitial Lung Disease

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected interstitial lung disease, including idiopathic pulmonary fibrosis, 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 genomic test 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 Envisia classifier was developed using RNA whole-transcriptome sequencing and machine learning to identify the usual interstitial pneumonia (UIP) pattern, which is a hallmark of IPF. The test assesses patient samples obtained through bronchoscopy, a nonsurgical procedure commonly used in lung evaluation, and is used as a complement to high-resolution computed tomography (HRCT). 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. 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 ability to achieve and maintain coverage from Medicare and state authorities for our tests, including the Envisia Genomic Classifier; the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, on the timing of the commercialization of the Percepta classifier, and on the size of Veracyte's addressable market. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; the benefits of our tests and 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 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 annual report on Form 10-K for the year ended December 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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Investor & Media Contact:
Angie McCabe
Vice President, Investor Relations & Corporate Communications
650-243-6371
angie@veracyte.com