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Veracyte Receives Final Medicare Coverage Policy for Envisia Genomic Classifier

Genomic Test is the First to Be Granted Medicare Coverage for Improved Diagnosis of Idiopathic Pulmonary Fibrosis (IPF)

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 4, 2019-- Veracyte, Inc. (Nasdaq: VCYT) announced today that it has received a final Medicare local coverage determination (LCD) for the Envisia™ Genomic Classifier. The policy was issued through the Palmetto GBA MolDx program and will become effective April 1, 2019, making the Envisia classifier covered for the nation's 55 million Medicare patients. The Envisia classifier is the first commercially available test of its kind to improve diagnosis of idiopathic pulmonary fibrosis (IPF) and is Veracyte's third genomic test to receive a Medicare-covered designation since the company's founding in 2008.

"We are pleased that the evidence supporting the Envisia classifier met the MolDx program's high standards for coverage," said   Bonnie Anderson, Veracyte's chairman and chief executive officer. "This important milestone will enable us to begin making the Envisia Classifier more widely available to patients with suspected IPF so that they can obtain an accurate, timely diagnosis and, in turn, appropriate treatment."

Over 100,000 people in the United States have lung-scarring interstitial lung diseases (ILDs), including IPF, which is the deadliest type, and the number is rising. While therapies are now available to slow progression of IPF, 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. Veracyte estimates that half of the patients evaluated for ILDs, including IPF, in the United States are covered by Medicare.

"A common theme in my conversations with other IPF patients is that we faced significant challenges in obtaining an accurate diagnosis," said Bill Vick, who founded the advocacy group PF Warriors after receiving an IPF diagnosis in 2011. "A tool that can provide more clarity in this diagnosis will alleviate anxiety for patients and, importantly, enable them to get appropriate treatment faster so that they have the potential to live longer, fuller, more productive lives."

About Interstitial Lung Disease

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected 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 the Envisia Genomic Classifier

The Envisia Genomic Classifier helps differentiate IPF from other ILDs without the need for surgery. The test is used as a complement to HRCT to enable clinicians to make a more confident diagnosis. Envisia evaluates patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation. The genomic test is proven to detect a genomic pattern of usual interstitial pneumonia (UIP), a hallmark of IPF, with high accuracy. In May 2018, Veracyte launched an Early Access Program to begin making the Envisia Genomic Classifier available to patients through select institutions around the country. To date, 30 leading institutions are participating in the program.

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 are developing by uniquely combining 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 Medicare coverage 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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