Veracyte Achieves Major Medicare Milestone for the Envisia Genomic Classifier

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First Test for Improved IPF Diagnosis Receives Draft Local Coverage Determination Through the MolDx Program

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 30, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced that it has received a draft Medicare local coverage determination (LCD) for the Envisia Genomic Classifier through the MolDx program. WPS Health Solutions posted a draft policy today, and the three other MACs (CGS, Noridian Health Solutions and Palmetto GBA) that participate in the Palmetto GBA-administered MolDx program are expected to issue similar LCDs. The Envisia classifier, which is built on next-generation RNA sequencing and machine learning technology, is the first test to achieve this significant Medicare coverage milestone for use in diagnosing idiopathic pulmonary fibrosis (IPF). Upon anticipated finalization, Envisia will become Veracyte's third genomic test to gain Medicare coverage since the company's founding in 2008.

Veracyte estimates that each year in the United States and Europe, up to 200,000 patients are evaluated for suspected interstitial lung diseases (ILD), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. Veracyte estimates that half of the patients evaluated in the United States are covered by Medicare.

"We applaud the MolDx program for taking this important step to make the Envisia classifier widely available to Medicare patients," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "The evidence supporting use of the Envisia classifier met MolDx's high bar for coverage and strongly positions us to expand commercialization of the test in 2019."

The draft policy is open to a 45-day comment period and Veracyte anticipates that the final policy will go into effect in early 2019. Veracyte's tests for improved diagnosis of thyroid cancer (Afirma) and lung cancer (Percepta) received Medicare coverage in 2012 and 2016, respectively.

"Timely, accurate diagnosis of IPF is essential so that patients can receive optimal treatment, including new therapies that can slow progression of this deadly disease," said Fernando J. Martinez, M.D., chief of the Division of Pulmonary and Critical Care Medicine at Weill Cornell Medicine, who is also a scientific advisor for Veracyte (the Envisia test maker). "Alas, IPF remains difficult to diagnose, with a challenge in distinguishing it from other interstitial lung diseases that can lead to diagnostic delay and, potentially, inappropriate therapy."

The Envisia Genomic Classifier helps differentiate IPF from other ILDs without the need for surgery. The test is used as a complement to high-resolution computed tomography (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 190-gene test detects a genomic pattern of usual interstitial pneumonia (UIP), a hallmark of IPF, with high accuracy (88 percent specificity and 70 percent sensitivity).

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. The company estimates that the market opportunity for the Envisia classifier in the United States and Europe is approximately $525 million.

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 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 (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 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: 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 June 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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