September 24, 2020

Veracyte Receives ADLT Status for Envisia Genomic Classifier From Centers for Medicare and Medicaid Services

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 24, 2020-- Veracyte, Inc. (Nasdaq: VCYT) announced today that the Centers for Medicare and Medicaid Services (CMS) has approved new Advanced Diagnostic Laboratory Test (ADLT) status for the Envisia® Genomic Classifier. The determination confirms that the Envisia classifier meets the criteria for ADLT status under the Protecting Access to Medicare Act of 2014 (PAMA), which is reserved for innovative products that provide novel clinical information that cannot be obtained by any other method. Veracyte's Envisia classifier is the first and only genomic test that helps improve diagnosis of idiopathic pulmonary fibrosis (IPF) and other interstitial lung diseases (ILDs).

Obtaining ADLT status initiates a specific, market-based approach to pricing the test for Medicare patients. For the six-month period beginning October 1, 2020 and ending March 31, 2021, Veracyte will collect private-payer payment rate data for the test, the median of which will be used by CMS to determine the Medicare pricing, beginning July 1, 2021. During the nine-month period prior to the new pricing, the Envisia classifier will be reimbursed at a rate of $5,500 for all Medicare patients. The Envisia classifier has been a covered benefit for Medicare patients since 2019.

"We believe that attaining ADLT status for the Envisia classifier is important because it underscores the test's novelty and value to patients, physicians and the healthcare system," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "Importantly, we believe this milestone also helps position the Envisia classifier for reimbursement expansion as we move into 2021 and beyond."

The Envisia classifier is the first and only commercially available genomic test that helps distinguish IPF from other ILDs, without the need for risky surgery. The classifier enables physicians to more confidently diagnose IPF when results from HRCT imaging are not definitive. Veracyte developed the Envisia classifier by combining RNA whole-transcriptome sequencing and machine learning to enable the detection of a genomic pattern of usual interstitial pneumonia (UIP), whose presence is essential to IPF diagnosis.

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected ILDs, including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of genomic tests leverage advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in thyroid cancer, lung cancer, breast cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping test is in development. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its tests to patients worldwide. 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, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the PROCURE study. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Envisia classifier provides clinical value that help physicians diagnose interstitial lung diseases, including idiopathic pulmonary fibrosis. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: Veracyte's ability to achieve and maintain Medicare coverage for its tests; the benefits of Veracyte's tests and the applicability of clinical results to actual outcomes Factors that may impact these forward-looking statements can be found in Item 1A – "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 25, 2020 and in our Quarterly Report on Form 10-Q filed with the SEC on July 30, 2020. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200924005232/en/

Investor and Media Contact:
Tracy Morris
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte