July 30, 2020

Veracyte Announces Data Published in AJRCCM Showing That the Envisia Genomic Classifier Improves Physicians' Ability to Diagnose IPF Without Surgery

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 30, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced new study results showing that use of the Envisia® Genomic Classifier improves physicians' ability to diagnose idiopathic pulmonary fibrosis (IPF) and other interstitial lung diseases (ILDs) without the need for surgery. The findings are published online in the *American Journal of Respiratory and Critical Care Medicine*, the journal of the American Thoracic Society, and confirm and expand on previously reported clinical validation results for the test.

For the study, researchers assessed the ability of the Envisia classifier to identify usual interstitial pneumonia (UIP) – the hallmark lung pattern of IPF – in transbronchial biopsy samples collected from a cohort of 96 prospectively enrolled patients undergoing evaluation for suspected ILD. These patients were part of the BRAVE study, which involved 30 centers in the United States and Europe.

The Envisia classifier demonstrated a specificity of 92.1 percent and a sensitivity of 60.3 percent, which is consistent with its previously reported clinical validation data. Additionally, when used as a complement to high-resolution CT (HRCT) imaging, the genomic test more than doubled the sensitivity for detecting UIP compared to HRCT alone (79.2 percent versus 34.0 percent) and increased the diagnostic yield by over 130 percent.

"Our findings demonstrate the Envisia classifier's ability to identify a UIP pattern of lung fibrosis in patients with ILD of unclear type, which can potentially facilitate earlier IPF diagnosis without the need for surgical lung biopsy," said Giulia C. Kennedy, Ph.D., chief scientific officer and chief medical officer of Veracyte and an author of the new publication. "Timely and accurate diagnosis of IPF and other ILDs becomes especially important given the availability of drugs to help slow the progression of IPF, as well as the increasing number of clinical trials for therapies that may potentially benefit patients with other types of ILD that feature the UIP pattern."

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.

"These new data further add to the growing body of clinical evidence demonstrating the performance and utility of the Envisia classifier in improving the diagnosis of IPF and other ILDs," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "We believe this comprehensive evidence will help facilitate physician adoption and payer reimbursement of our test, making it more accessible to patients in the United States, as well as in global markets where we plan to introduce the Envisia classifier in 2021."

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. A survey conducted by the Pulmonary Fibrosis Foundation showed that 55 percent of IPF/ILD patients are misdiagnosed at least once and, for one in five patients, accurate diagnosis took three or more years.

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" 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, statements regarding the Envisia classifier's ability to facilitate earlier IPF diagnosis and distinguish IPF from other interstitial ILDs, and Veracyte's expectations regarding physician adoption of the Envisia classifier. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: the impact of COVID-19 on Veracyte's business and operating results, specifically, and the healthcare system and economy more generally, 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; the laws and regulations applicable to Veracyte's business, including potential regulation by the Food and Drug Administration or other regulatory bodies; Veracyte's ability to successfully achieve and maintain adoption of and reimbursement for its products; the amount by which use of Veracyte's 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 Veracyte's filings with the Securities and Exchange Commission, including the risks set forth in its quarterly report on Form 10-Q for the quarter ended March 31, 2020. 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/20200730005341/en/

Investor and Media Contact:

Tracy Morris
Vice President of Corporate Communications
& Investor Relations
650-380-4413
tracy.morris@veracyte.com

Source: Veracyte, Inc.