May 14, 2021

Veracyte Announces Data Reinforcing the Diagnostic Performance and Utility of the Envisia Genomic Classifier in ILD Diagnosis

New findings presented at ATS 2021 Conference also suggest novel test can be successfully enabled on nCounter Analysis System to support international expansion

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 14, 2021-- Veracyte, Inc. (Nasdaq: VCYT) announced that data reinforcing the diagnostic performance and utility of the Envisia® Genomic Classifier are being shared at the American Thoracic Society (ATS) 2021 International Conference, taking place today through May 18. The company is also presenting new data which demonstrate that the novel genomic test can be successfully enabled on the nCounter Analysis System, supporting the company's plans to make the novel test – for improved diagnosis of interstitial lung diseases (ILDs) – available to physicians and their patients in global markets.

Each year in the United States and Europe, up to 220,000 patients are evaluated for suspected ILDs, including idiopathic pulmonary fibrosis (IPF), which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. The Envisia Genomic Classifier detects a genomic pattern of usual interstitial pneumonia (UIP) to improve ILD diagnostic and prognostic confidence. The test is performed in Veracyte's U.S.-based CLIA laboratory. The company plans to be ready to make the Envisia classifier available on the nCounter Analysis System in international markets by the end of this year, which will enable laboratories to perform the test locally.

In one Envisia-related poster presented today, researchers assessed the classifier's ability to detect UIP among a subset of ILD patients with clinical characteristics that are less commonly associated with IPF (<65 years of age, female, never smokers) and therefore make them especially challenging to diagnose. Researchers retrospectively analyzed 144 samples from ILD patients enrolled in two prior, independent clinical validation cohorts. Findings showed that, across all groups, the Envisia classifier had a 90.6% specificity (CI: 80.7, 96.5) and 62.5% sensitivity (CI: 51.0, 73.1), as compared to histology-proven UIP, and that there were no significant differences when the cohorts were stratified by gender, age and smoking status.

"These findings demonstrate robust performance of the Envisia Genomic Classifier across subsets of patients who are typically less likely to have a UIP pattern or IPF," said Luca Richeldi, M.D., Ph.D., of Università Cattolica del Sacro Cuore, who presented the data. "This is the first time that study data have been stratified to look at clinical characteristics in this way, and I think physicians will be reassured to learn that the Envisia classifier's sensitivity and specificity extend to patients who are less likely to have IPF and therefore typically harder to diagnose confidently."

Additionally, new data presented today suggest that the Envisia classifier may soon be accessible to physicians and patients in global markets via the nCounter Analysis System. Veracyte acquired exclusive global diagnostics rights to the molecular testing platform in December 2019, with plans to facilitate global access to its tests – starting with the Envisia classifier.

Veracyte researchers tested the Envisia classifier's clinical performance on the nCounter system. They then processed 33 transbronchial biopsy (TBB) samples of varying RNA quality on both an RNA-sequencing platform, which is used in the company's centralized lab in the U.S., and the nCounter system, using the validated Envisia classifier set of 190 genes. Results show high correlation between the nCounter and RNA-sequencing platforms, suggesting that the classifier's clinical performance will be maintained on the nCounter system.

"Making our validated genomic tests available on the nCounter system will enable physicians and patients around the world to access timely, critical diagnostic information that can change the path of patients' disease and lives," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "We are excited to execute on this plan, beginning with the Envisia classifier."

Multiple abstracts relating to the Envisia Genomic Classifier can be viewed at the links below. The presentations are available on demand to ATS conference registrants through July 2:

Title: Envisia Genomic Classifier Demonstrates Consistent Performance Across Gender, Age Group, and Smoking Status. Abstract #A1839
First Author: Luca Richeldi, M.D., Ph.D., Università Cattolica del Sacro Cuore, Rome, Italy

Title: Envisia Genomic Classifier Helps Improve Multidisciplinary Diagnoses of Complex Interstitial Lung Diseases. Abstract #A1877
First Author: Lisa H. Lancaster, M.D., Vanderbilt University Medical Center

Title: Bridging the Envisia Genomic Classifier to the nCounter Platform: A Proof-of-Concept Study. Abstract #A4352
First Author: Huimin Jiang, Ph.D., Veracyte

Title: Cryobiopsy and Genomic Classifier (Envisia) in the Diagnosis of Usual Interstitial Pneumonia. Abstract #A4236
First Author: R. Ronaghi, M.D., University of California, Los Angeles

Title: Role of the Envisia Genomic Classifier in Establishing a Diagnosis of Idiopathic Pulmonary Fibrosis. Abstract #1837
First Author: M. Abdalla, M.D., Pulmonary and Critical Care Medicine, Medical College of Wisconsin

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 lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are 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 Envisia Genomic Classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "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 test provides clinical value that helps physicians diagnose and treat IPF, and the ability of Veracyte to expand the menu of advanced genomic tests on the nCounter Analysis System. 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. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. These forward-looking statements speak only as of the date hereof and, except as required by law, 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.

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