New Data Suggest Veracyte’s Envisia Genomic Classifier Can Help Predict Disease Progression in Interstitial Lung Disease Patients Treated with Combination Immunosuppressive Therapy

Findings presented at the European Respiratory Society International Congress 2022

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 7, 2022-- Veracyte, Inc. (Nasdaq: VCYT) today announced new data suggesting that the Envisia Genomic Classifier (EGC) can help predict which patients with interstitial lung disease (ILD), including idiopathic pulmonary fibrosis (IPF), are likely to have progressive disease that declines with combination immunosuppressive therapy. These findings, shared at the European Respiratory Society (ERS) International Congress 2022 (Abstract #PA1948), are important because they show that the genomic test can help physicians make more-informed treatment decisions for their patients.

“Patients with IPF and other progressive ILDs are recommended for antifibrotic therapy,” said Athol Wells, M.D., Ph.D., consultant chest physician at Royal Brompton Hospital in London who presented the new findings in a poster presentation. “However, determining which patients have IPF or an ILD that will progress is often challenging. This can lead to treatment delays or, worse, empirical treatment with immunosuppressant therapy that may be harmful to some patients with progressive disease. Our findings suggest that the Envisia Genomic Classifier can identify patients whose ILD is likely to progress with combination immunosuppressive therapy and who thus could potentially benefit from antifibrotic therapy.”

The Envisia test identifies a genomic pattern of usual interstitial pneumonia (UIP), a critical factor in distinguishing IPF from non-IPF to help guide initial treatment, using tissue obtained through transbronchial biopsy. In the study, the researchers retrospectively analyzed data from 135 patients enrolled in the BRAVE trial who underwent evaluation for an undiagnosed ILD, had an EGC result and had multiple forced vital capacity (FVC) measurements to assess lung function over time.

They found that patients with an EGC-positive result for UIP who had been treated with combination immunosuppressive therapy demonstrated a greater decline in lung function (9.4%) compared to a decline of 1.9% among patients who did not receive combination immunosuppressive therapy. Meanwhile, patients who were EGC-negative for UIP did not show a significant difference in 1-year FVC change among those taking combination immunosuppressive therapy compared to those not treated with both (1.9% decline vs. 0.3% increase, respectively). Findings were similar independent of the pathologic diagnosis, suggesting that the genomic signal of UIP may reflect the basic biology of progression independent of pathologic manifestations of disease.

“These findings highlight how Veracyte’s Envisia Genomic Classifier can provide information that goes beyond diagnosing IPF, providing valuable insights that suggest how ILD patients may respond to different treatment options,” said Bill Bulman, M.D., Veracyte’s medical director, Pulmonology, and one of the study authors. “These results further support the clinical utility of the Envisia test, highlighting its potential to help inform diagnosis, prognosis, and treatment decisions by identifying patients with UIP, helping some patients avoid potentially harmful therapy.”

Veracyte currently performs the Envisia test in its centralized laboratory in the United States. The company plans to offer the test as an in vitro diagnostic (IVD) that can be performed locally by laboratories for physicians and their patients in global markets. Veracyte plans to submit the Envisia IVD test for regulatory approval in Europe in 2023 and begin making it available commercially following such approval.

About Veracyte
Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions. Our growing menu of advanced diagnostic tests help patients avoid risky, costly procedures and interventions, and reduce time to appropriate treatment. In addition to making our tests available in the United States through our central laboratories, our exclusive license to our best-in-class diagnostics instrument (nCounter Analysis System) positions us to deliver our tests to patients worldwide through laboratories that can perform them locally. 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 our clinical tests in and outside of the United States. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plans," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. An example of a forward-looking statement includes, among others, that data presented at ERS suggests that the Envisia Genomic Classifier can help predict which patients with ILD, including those with IPF, are likely to have progressive disease and that the genomic test can help physicians make more informed treatment decisions for their patients. 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 on February 28, 2022, and our Quarterly Report on Form 10-Q to be filed for the three months ended June 30, 2022. Copies of these documents, when available, may be found in the Investors section of our website at www.investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim 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.

Veracyte, the Veracyte logo, Decipher and Prosigna are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries. nCounter is the registered trademark of NanoString Technologies used by Veracyte under license.

Veracyte delivers the Decipher Prostate Genomic Classifier from its CLIA laboratories. Those tests are not CE-IVD marked and have not been cleared or approved by the FDA; their performance characteristics were determined by Veracyte and they might be considered for Research Use Only in some markets. Please contact Veracyte for confirmation. This piece is distributed purely for educational purposes and is not intended to promote or encourage any off-label use of Veracyte products.
Investors:
Shayla Gorman
Director, Investor Relations
investors@veracyte.com
619-393-1545

Media:
Tracy Morris
Vice President, Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.