CORRECTING and REPLACING Veracyte and Yale Announce Exclusive License to Advance First Genomic Monitoring Test for Idiopathic Pulmonary Fibrosis

April 23, 2020

- Non-Invasive, Blood-Based Test Could Help Inform Key Treatment Decisions -

SOUTH SAN FRANCISCO, Calif. & NEW HAVEN, Conn.--(BUSINESS WIRE)--Apr. 23, 2020-- Second paragraph, first sentence of release should include Dr. Jose Herazo-Maya, currently Director of Interstitial Lung Disease Program NCH Healthcare System, Naples, Fla.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200423005227/en/

The corrected release reads:

VERACYTE AND YALE ANNOUNCE EXCLUSIVE LICENSE TO ADVANCE FIRST GENOMIC MONITORING TEST FOR IDIOPATHIC PULMONARY FIBROSIS

- Non-Invasive, Blood-Based Test Could Help Inform Key Treatment Decisions -

Veracyte, Inc. (Nasdaq: VCYT) and Yale University today announced an exclusive licensing agreement to advance the first genomic test for predicting disease progression in patients with idiopathic pulmonary fibrosis (IPF). The agreement gives Veracyte rights to a 52-gene signature developed by Yale researchers, for use on the nCounter FLEX Analysis System – Veracyte's exclusively licensed diagnostics platform. Veracyte plans to make the non-invasive, blood-based test available as a complement to its Envisia Genomic Classifier, as part of a comprehensive offering to aid in the diagnosis and treatment of patients with IPF.

The 52-gene signature in peripheral blood, developed by Dr. Naftali Kaminski, chief of the Section of Pulmonary, Critical Care and Sleep Medicine in the Department of Medicine at Yale University's School of Medicine, Dr. Jose Herazo-Maya, currently Director of Interstitial Lung Disease Program NCH Healthcare System, Naples, Fla. and collaborators*, is shown to predict rapid disease progression among patients with IPF. In a study published in *Science Translational Medicine*, the genomic profile was substantially more accurate at identifying patients with poor outcomes as compared to a traditional assessment using clinical variables. The findings were subsequently validated in an international multicenter study published in *Lancet Respiratory Medicine*.

"We are excited to advance groundbreaking research from Dr. Kaminski and his team into a commercially available, first-of-its-kind genomic test that may further help guide care for patients with IPF," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "The addition of prognostic information to our Envisia classifier, which is already available as a genomic tool to help improve IPF diagnosis, enhances the value of this test for physicians and patients as we prepare it for global market expansion on the nCounter platform in 2021. This agreement was enabled by Veracyte's December 2019 acquisition of the exclusive global diagnostics rights to the nCounter platform, and further underscores the strategic value of that transaction to our company."

Each year in the United States and Europe, up to 200,000 patients are evaluated for suspected interstitial lung diseases (ILDs), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. Median survival following IPF diagnosis is approximately 2.5 to 3.5 years. In recent years, antifibrotic therapies have helped extend survival for some patients.

"The clinical implications of predicting outcomes in IPF are substantial," said Dr. Kaminski. "For example, knowing which patients are likely to rapidly progress could allow more accurate and timely referral to appropriate treatments. The implications for clinical trials and new drugs coming to the patients are also important because information about individual patients' potential outcomes will allow better stratification of patients for trials and eventually tailoring of IPF therapies."

Veracyte and Yale University also announced a research agreement with Dr. Kaminski's lab aimed at further elucidating the genomic underpinning of interstitial lung diseases (ILDs), with the potential to further inform diagnosis and treatment decisions for patients with ILDs, including IPF.

"IPF is an overwhelming diagnosis for many patients and their caregivers," said Dr. Gregory Cosgrove, chief medical officer of the Pulmonary Fibrosis Foundation. "Any additional, reliable information we can provide regarding their personal disease status will not only help guide important decisions, including individual treatment plans, but could help reduce anxiety and fear."

About Envisia

The Envisia Genomic Classifier is the first commercially available test to improve the diagnosis of IPF. The genomic test enables physicians to more confidently differentiate IPF from other ILDs, helping to guide an optimal patient treatment plan that can improve outcomes and reduce risk. The Envisia classifier was developed using RNA whole-transcriptome sequencing and machine learning to identify the usual interstitial pneumonia (UIP) pattern, which is a hallmark of IPF. The test assesses patient samples obtained through bronchoscopy, a nonsurgical procedure commonly used in lung evaluation, and is used as a complement to high-resolution computed tomography (HRCT). The Envisia classifier is proven to detect UIP with high correlation to the gold standard – histopathology results read by ILD experts – without the need for surgery.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing answers to clinical questions that inform diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. The company's core products are uniquely developed with RNA whole-transcriptome sequencing and machine learning to deliver results that give patients and physicians a clear path forward. Since its founding in 2008, Veracyte has commercialized seven genomic tests and is transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. In December 2019, Veracyte acquired the exclusive global diagnostic rights to the nCounter platform from NanoString Technologies, Inc., through which it plans to make its genomic tests available to physicians and their patients worldwide. These include commercial and in-development tests in breast cancer and lymphoma, respectively, which Veracyte also acquired through the transaction. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

About the Yale Office of Cooperative Research:

Since its founding in 1982, the Yale Office of Cooperative Research (OCR) has built a significant portfolio of inventions and patents and has grown into an engine of regional economic development. Its mission is to facilitate the translation of research from Yale's labs into products and services that benefit society. OCR is recognized as a leading force for catalyzing economic growth by identifying, counseling and nurturing early-stage technologies and guiding the transition into robust companies.

More information is available at https://ocr.yale.edu.

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 Veracyte's expectations regarding the ability of the new genetic signature to advance the first genomic test for predicting disease progression in patients with IPF, the expected impacts of the acquisition from NanoString on Veracyte, including its ability to expand its platform globally, its ability to increase the efficiency of its advanced genomic testing, and its plans to transfer its current and pipeline genomic tests onto the nCounter system; Veracyte's ability to advance the development and commercialization of novel diagnostic tests under the collaboration with Johnson & Johnson; the ability of Veracyte to achieve the expected benefits from the Acerta collaboration; and its ability to potentially inform diagnosis and treatment decisions in new oncology indications. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. 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 our 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 annual report on Form 10-K for the year ended December 31, 2019. 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.

*Original collaborators included Dr. Imre Noth, University of Virginia; and Dr. Joe G. N. "Skip" Garcia, University of Arizona College of Medicine – Tucson.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200423005227/en/

For Veracyte:

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

For Yale University:

Michelle McQueen
Communications Officer
Office of Cooperative Research
203-432-1998 o
917-370-6016 c
michelle.mcqueen@yale.edu

Source: Veracyte, Inc.