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New Data Demonstrating Ability of Veracyte's Genomic Test to Improve Idiopathic Pulmonary Fibrosis Diagnosis Presented at ATS 2016

-- Three other studies reinforce potential for the Envisia™ classifier to positively impact clinical decision-making --

SOUTH SAN FRANCISCO, Calif., May 17, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced findings from a new study demonstrating the potential for the company's in-development Envisia classifier to help distinguish idiopathic pulmonary fibrosis (IPF) from other interstitial lung diseases (ILD) without the need for invasive and potentially risky surgery. Additional data from three other studies suggest the potential for the test to address several challenges that currently hinder accurate and timely diagnosis of the disease. The findings were presented at the American Thoracic Society (ATS) 2016 International Conference taking place May 13-18 in San Francisco.

Each year in the United States and Europe, up to 200,000 patients are suspected of having an ILD, including IPF, which is among the most common and most deadly of these lung-scarring diseases. IPF is notoriously difficult to diagnose, often leading to treatment delays, prolonged misdiagnosis, patient distress and added healthcare expense.

Data presented at the ATS conference suggest the Envisia classifier's accuracy in identifying patients with IPF and its potential to improve upon traditional high-resolution CT (HRCT) imaging evaluation alone. Using 211 samples obtained from 59 patients through less-invasive transbronchial biopsy (TBB), researchers developed a prototype genomic classifier, which uses deep RNA sequencing, to accurately distinguish the presence of usual interstitial pneumonia (UIP) - a pathology pattern whose presence is essential to IPF diagnosis - from samples without UIP. In an independent test set of 35 patients with up to five TBB samples from each, the prototype classifier correctly identified a majority of samples as UIP from 20 patients with a UIP pattern confirmed by pathology (93 percent sensitivity; 58 percent specificity). In contrast, HRCT confidently identified only 5 of 19 patients (26 percent) with a UIP histopathologic pattern.

"Physicians traditionally use HRCT imaging to diagnose IPF, but results can be ambiguous and surgical lung biopsy (SLB) is often needed to obtain a more definitive diagnosis," said Giulia C. Kennedy, Ph.D., chief scientific officer of Veracyte, who presented the data. "These findings are significant because they suggest that the Envisia classifier may potentially help improve IPF diagnosis and reduce the need for surgery in patients with suspected ILD. This is particularly important because these patients are often too frail to undergo such an invasive procedure."

Data from a second study presented at the ATS conference suggest the potential for the Envisia classifier to improve clinical decision-making in IPF diagnosis, particularly in community-based settings. Among 96 prospectively collected biopsy samples from 56 patients with suspected ILD, local pathologists missed more than one third (34 percent) of IPF cases, compared with expert pathology identification (via a centralized pathology review group) of UIP, which served as "truth."

"IPF diagnosis can be challenging for physicians in all types of settings. However, in this study, community-based pathologists missed a substantial number of IPF diagnoses compared to experts who specialize in diagnosing the disease, potentially impacting treatment for patients diagnosed at the local level," said Dr. Kennedy, one of the study authors. "This suggests that a diagnostic tool with high sensitivity for UIP could be particularly helpful to physicians who do not have access to expert pathology review."

In a third study presented at the ATS conference, researchers from Weill Cornell Medical College and The University of Michigan shared physician survey data suggesting the potential ability of Veracyte's genomic classifier to reduce the need for invasive diagnostic procedures and increase appropriate treatment for IPF. Two drugs are now available to, for the first time, slow progression of this deadly disease.

In a fourth study (to be presented Wednesday, May 18, 9:00-11:00 a.m. PT), researchers from the Pulmonary Fibrosis Foundation will present findings of the organization's recent survey - sponsored by Veracyte - of patients diagnosed with IPF or another ILD, which quantified the staggering rate of diagnostic delays, misdiagnoses and often invasive procedures.

"We believe that the Envisia classifier will help transform care among the hundreds of thousands of patients who present each year with a suspected ILD," said Bonnie Anderson, president and chief executive officer of Veracyte. "A growing body of data suggests that Envisia has the potential to both reduce the time required for patients to receive an accurate diagnosis and to reduce the number of patients who must undergo risky, invasive surgeries to obtain such a diagnosis." Veracyte plans to launch the Envisia classifier in the fourth quarter of 2016.

About Veracyte

Veracyte (NASDAQ: VCYT) is pioneering the field of molecular cytology, offering genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. By improving preoperative diagnostic accuracy, the company aims to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's Afirma® Thyroid FNA Analysis centers on the proprietary Afirma Gene Expression Classifier (GEC) and is becoming a new standard of care in thyroid nodule assessment. The Afirma test is recommended in leading practice guidelines and is covered for 180 million lives in the United States, including through Medicare and many commercial insurance plans. Veracyte is expanding its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. In April 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer. In the fourth quarter of 2016, Veracyte plans to launch its second pulmonology product, the Envisia classifier, to improve diagnosis of interstitial lung diseases including idiopathic pulmonary fibrosis. For more information, please visit www.veracyte.com.

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 we make regarding our beliefs regarding the drivers of adoption of Afirma, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2016 guidance and forecast for annual GEC test volume, and the value and potential of our technology and research and development pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our limited operating history and history of losses; our ability to increase usage of and reimbursement for Afirma and to obtain reimbursement for any future products we may develop or sell; our ability to continue our momentum and growth; our dependence on a few payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our tests; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on strategic relationships and our ability to successfully convert new accounts resulting from such relationships; our ability to develop and commercialize new products and the timing of commercialization; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; the timing and publication of study results; the applicability of clinical results to actual outcomes; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; our ability to expand into international markets and achieve adoption of our tests in such markets; our ability to obtain capital when needed; and other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.