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Veracyte Announces New Data Supporting Advancement of Its IPF Program Presented Today at PFF Summit 2015

-- Progress in Molecular Classifier Development --
-- Potential Clinical Utility of a Molecular Test that Distinguishes IPF from Other ILDs --
-- Need for Improved IPF Diagnosis and Treatment Approaches Among Pulmonologists --

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced that studies supporting the advancement of its idiopathic pulmonary fibrosis (IPF) program were presented today at the *PFF Summit 2015: From Bench to Bedside,* being held in Washington, DC.

Each year in the United States and Europe, up to 200,000 patients are suspected of having an interstitial lung disease (ILD), including IPF, which is among the most common and most deadly. IPF is often difficult to diagnose without surgical lung biopsy (SLB), which is invasive, expensive and potentially risky. In October 2014, the US Food and Drug Administration approved the first two drugs demonstrated to slow IPF disease progression among some patients - increasing the importance of accurate and timely diagnosis for all patients with suspected IPF.

In the first study, company researchers presented data suggesting that Veracyte's molecular classifier, which is in development, has the potential to accurately distinguish IPF from other ILDs without the need for surgery. Using 135 samples obtained through less-invasive transbronchial biopsy (TBB), Veracyte researchers demonstrated the classifier's ability to accurately distinguish the presence of usual interstitial pneumonia (UIP), a pathology pattern whose presence is essential to IPF diagnosis, from samples without UIP (area under curve of 93 percent). The classifier is being developed using whole-genome, deep RNA sequencing and with training by histopathology "truth." These results reinforce previous findings[1].

"IPF is notoriously difficult to diagnose, often leading to treatment delays, prolonged misdiagnoses, patient distress and added healthcare expense. While surgery is considered the 'gold standard' for diagnosis, many patients are too frail to undergo such an invasive procedure," said Bonnie Anderson, president and chief executive officer of Veracyte. "We are extremely encouraged by our results and the potential for Veracyte's molecular classifier to offer physicians a valuable tool to help resolve ambiguity in ILD and IPF diagnoses. We look forward to even further refining the test, based on our powerful, deep RNA sequencing approach." Veracyte plans to launch the molecular classifier in 2016.

In the second study presented today, researchers from Weill Cornell Medical College and The University of Michigan revealed findings from a national survey of 76 pulmonologists from ILD centers and non-specialty clinics, which demonstrate the potential utility of Veracyte's molecular classifier to reduce the need for invasive diagnostic procedures and increase appropriate treatment for IPF. The survey described a genomic test with high precision for identifying a UIP pattern using samples collected through bronchoscopy and then asked physicians to evaluate how the classifier would change their management of four ILD patient cases of varying degrees of diagnostic ambiguity, with imaging and clinical history available (confident UIP, possible UIP, possible UIP vs. hypersensitivity pneumonitis, and connective tissue disease-related ILD).

Overall, 85 percent of physicians said they would use the genomic test if it required TBB, vs. just 63 percent if the test required SLB. Physicians also reported that availability of the molecular classifier would reduce their use of SLB by more than half (from 33 percent to 16 percent) in cases of "possible UIP." At the same time, physicians reported that a positive IPF test result would increase treatment with one of the two new IPF drugs for both "possible UIP" cases (from 11 percent to 46 percent) and "confident UIP" cases (from 47 percent to 70 percent).

"These findings reinforce the challenges physicians face in diagnosing IPF and that there is a significant need for better diagnostic approaches to ensure optimal treatment of our IPF patients," said Fernando J. Martinez, M.D., of Weill Cornell Medical College, who co-authored the study. "Utilization of better diagnostic tools may decrease the need for invasive procedures and increase appropriate diagnosis and the timely treatment of IPF. This is especially important given the availability of therapies that slow the disease's physiological progression."

The third study assessed the degree to which ILD specialists differ from non-specialist pulmonologists in decision-making in the

diagnosis and treatment of ILDs. Among the findings, ILD specialists recommended IPF therapies without a TBB or SLB significantly more often than non-specialty pulmonologists when imaging and clinical history were consistent with IPF (81 percent vs. 38 percent). In addition, in the two "possible UIP" cases, both ILD specialists and non-specialists had high rates of recommending SLB (44 percent and 50 percent, respectively, among ILD specialists and 30 percent in both cases by non-specialists), reinforcing the need for a less invasive approach for IPF diagnosis in both community and specialty settings.

Separately, the Pulmonary Fibrosis Foundation (PFF) announced and presented today findings from a recent survey of 600 American adults with ILDs and/or IPF. The survey, which was supported by Veracyte, quantifies a staggering rate of diagnostic delays, misdiagnoses and often invasive procedures. More information can be found here.

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 nearly 155 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 t evaluate patients with lung nodules that are suspicious for cancer. Veracyte is developing a second product in pulmonology, targeting 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 2015 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 September 30, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

[1] Kim, SY. (June 2015). Classification of usual interstitial pneumonia in patients with interstitial lung disease: assessment of a machine learning approach using high-dimensional transcriptional data. *Lancet Resp. Med.*, 3(6), 473-482.