

May 20, 2015

Veracyte Presents Preliminary Data Demonstrating Ability of Molecular Classifier to Improve Non-Surgical IPF Diagnosis Using Bronchoscopy Samples

Presentation at American Thoracic Society 2015 International Conference concurrent with The Lancet Respiratory Medicine publication highlighting foundational research that informed classifier development

SOUTH SAN FRANCISCO, Calif., May 20, 2015 /PRNewswire/ -- <u>Veracyte, Inc</u>. (NASDAQ: VCYT) today presented preliminary data demonstrating the ability of the company's molecular classifier to help distinguish idiopathic pulmonary fibrosis (IPF) from other interstitial lung diseases (ILDs) using samples obtained through bronchoscopy. The findings suggest the classifier's potential to help thousands of patients avoid invasive, risky and expensive surgery to resolve ambiguity in IPF diagnosis - a frequent challenge for physicians and patients.

The data were presented today at the American Thoracic Society (ATS) 2015 International Conference in Denver, Colo. The presentation coincides with online publication in *The Lancet Respiratory Medicine* of an article detailing foundational work and results from an independent test set, which demonstrated classifier performance using patient tissue samples obtained through surgery.

The data shared at ATS today demonstrate the ability of a Veracyte molecular classifier to distinguish the presence of a specific pathology pattern that is a hallmark of IPF among samples obtained through transbronchial bronchoscopy (TBB). This pathology pattern - whose presence is essential to IPF diagnosis - is often difficult to distinguish without surgery. Using whole-genome data and classifiers trained by histopathology "truth," researchers developed a classifier that could distinguish this pattern with high specificity (92 percent), suggesting its ability to identify and distinguish IPF from other ILDs, including non-specific interstitial pneumonia, emphysema and organizing pneumonia.

Each year in the United States and Europe, up to 200,000 patients are suspected of having an ILD, including IPF, which is the most common and most deadly, and is difficult to diagnose.

"The recent availability of therapies that slow progression of IPF makes improved diagnosis of this disease even more imperative," said Giulia C. Kennedy, Ph.D., chief scientific officer of Veracyte, who presented the data. "The findings presented today suggest it is possible to develop a molecular test that will enable less invasive and more accurate diagnoses of IPF. These results move us one step closer to making such a test available to patients who could greatly benefit from it."

Concurrent with the ATS presentation, *The Lancet Respiratory Medicine* published results from key original proof-of-concept research validating Veracyte's rigorous genomic approach to IPF diagnosis. Using 125 surgical lung biopsy samples from 11 hospitals across North America, researchers performed a series of statistical analyses to confirm that a genomic signal differentiating IPF can be identified using trained genomic classifiers.

"Taken together, findings from these studies confirm the potential of a genomic test to help physicians differentiate and diagnose IPF," said Dr. Kennedy. "We look forward to further improving our molecular classifiers by increasing the number of patient samples and incorporating additional information, such as radiologic and clinical information, into the algorithm."

About Veracyte

Veracyte (NASDAQ: VCYT) is pioneering the field of molecular cytology, focusing on 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 first commercial solution, the Afirma[®] Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis 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 150 million lives in the United States, including through Medicare and many commercial insurance plans. Veracyte intends to expand 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 resolve preoperative ambiguity in lung nodules that are suspicious for cancer. Veracyte is also developing a second product in pulmonology, targeting interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visit <u>www.veracyte.com</u>.

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 our tests, our expectations with respect to our entry into the pulmonology market, our beliefs regarding the benefits and attributes of our pulmonology tests, 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. Forwardlooking 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 t our current tests and any future tests 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, uncertainty 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 federal and state 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 introduce and achieve adoption of our tests; our ability to obtain reimbursement for our tests; 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; 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 guarter ended March 31, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

Veracyte, Afirma, Percepta, the Veracyte logo, and the Afirma logo are trademarks or registered trademarks of Veracyte, Inc.

Media:

Tracy Morris 650-380-4413 tracy.morris@veracyte.com

Michele Parisi 925-864-5028 mparisi@forwardhealthinc.com

Investors:

Pam Lord Canale Communications 619-849-6003 (o) 619-459-1629 (m) pam@canalecomm.com

To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/veracyte-presents-preliminary-data-demonstrating-ability-of-molecular-classifier-to-improve-non-surgical-ipf-diagnosis-using-bronchoscopy-samples-300086277.html</u>

SOURCE Veracyte

News Provided by Acquire Media