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Veracyte Announces Publication of Data Supporting Clinical Utility of the Percepta® Bronchial Genomic Classifier in Lung Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced that data supporting the ability of the company's Percepta Bronchial Genomic Classifier to help reduce unnecessary, invasive procedures in lung cancer diagnosis were published online in *CHEST*, the official journal of the American College of Chest Physicians.

Utilizing data from two prospective, multicenter studies,[1,2] researchers determined that use of the Percepta classifier could have decreased unnecessary, invasive procedures in 50 percent of the evaluated patient population. The study analyzed patients with lung nodules or lesions whose bronchoscopy results were inconclusive for cancer and who were considered to have an intermediate or low risk of cancer prior to use of the Percepta classifier. The genomic test has previously been shown to have high accuracy when it identified lung nodules or lesions as low risk for cancer among this population.

"As the number of lung nodules and lesions are increasing due to both incidental findings and expanding lung cancer screening programs, providers need clinically proven tools to help them more confidently determine which patients can be followed with CT scans and avoid additional, invasive and potentially risky tests," said Anil Vachani, M.D., University of Pennsylvania School of Medicine and lead author of the *CHEST* paper. "Our findings suggest that use of the Percepta classifier may help reduce the frequency and associated morbidity of invasive procedures in lung cancer diagnosis."

Among the 188 patients evaluated in the study, 77 underwent at least one invasive procedure and 42 of these were ultimately determined to have benign disease. Researchers concluded that, had the Percepta classifier been used to guide decision making, 50 percent of the patients with benign disease could have avoided unnecessary, invasive procedures. The findings are based on the premise that a negative classifier result would have prompted physicians to follow patients with CT scans instead of proceeding to more-invasive diagnostic approaches.

"Unnecessary procedures resulting from diagnostic ambiguity are costly in many ways for patients, medical professionals and our healthcare system," said Bonnie Anderson, president and chief executive officer of Veracyte. "Given that more than one and a half million incidental nodules are discovered every year and an additional eight million Americans recently became eligible for annual lung cancer screening, we are extremely pleased that the Percepta Bronchial Genomic Classifier is demonstrating the ability to help patients avoid risky, invasive procedures on nodules that are actually likely benign. We believe this also will help reduce costs for the healthcare system."

An estimated 250,000 patients currently undergo a bronchoscopy, a common nonsurgical procedure, for suspected lung cancer each year in the United States. Approximately 40 percent of bronchoscopies produce inconclusive results, which can lead to risky and expensive invasive procedures such as transthoracic needle biopsy (TTNB) and surgical lung biopsy (SLB). TTNB, for example, has a 15 to 25 percent risk of collapsed lung; SLB is estimated to cost more than $20,000.

About Percepta

The Percepta Bronchial Genomic Classifier is designed to identify patients with lung nodules who are at low risk of cancer following an inconclusive bronchoscopy result, to enable these patients to be safely monitored with CT scans in lieu of invasive diagnostic procedures. The 23-gene molecular classifier's performance is proven in clinical validation studies enrolling more than 1,000 patients, including strong data published in *The New England Journal of Medicine*. The classifier uses proprietary genomic technology to detect molecular changes that occur in the epithelial cells lining the lung's respiratory tract in current or former smokers with lung cancer. These changes can be detected in cells obtained from standard cytology brushings taken during bronchoscopy from the mainstem bronchus and indicate the presence of malignancy or disease processes from distant sites in the lung. Thus, the test is designed to determine a lung nodule's or lesion's likelihood of cancer, without the need to sample the nodule or lesion directly. The Percepta test is performed at Veracyte's CLIA-certified laboratory in South San Francisco, California.

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 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 175 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. 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] Silvestri GA, Vachani A, Whitney D, et al. .A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer**.** *N Engl J Med*. 2015.

[2] Whitney DH, Elashoff MR, Porta K, et al. Derivation of a bronchial genomic classifier for lung cancer in a prospective study of patients undergoing diagnostic bronchoscopy. *BMC Medical Genomics*. 2015, 8:18.