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Veracyte Announces Presentation of Percepta™ Bronchial Genomic Classifier Clinical Validation Data at the 16th World Conference on Lung Cancer

SOUTH SAN FRANCISCO, Calif., Sept. 9, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced the presentation of data supporting the use of the Percepta Bronchial Genomic Classifier to help reduce unnecessary, invasive biopsies as part of lung cancer diagnosis. The findings will be presented today at the 16th World Conference on Lung Cancer, being held in Denver, Colo., September 6-9, 2015.

The multicenter study involved 163 current or former smokers who were undergoing bronchoscopy to evaluate lung nodules or lesions that were suspicious for cancer. Among the 123 patients whose bronchoscopy results were inconclusive - meaning that cancer could not be ruled out - the Percepta test identified patients at low risk of cancer with a high level of accuracy (negative predictive value of 94 percent). The genomic test and bronchoscopy had a combined ability to detect cancer (*i.e.*, sensitivity) of 96 percent, compared to 51 percent for bronchoscopy alone. The findings being presented today appeared previously in a journal article describing the Percepta test's development.[1]

"Bronchoscopy is among the most common methods for evaluating suspicious lung nodules or lesions, but it frequently produces inconclusive results. This leaves physicians with the dilemma of whether to subject patients to invasive, expensive and potentially unnecessary diagnostic procedures or just monitor them, with the chance that they may have cancer," said Anil Vachani, M.D., associate professor of medicine at the Perelman School of Medicine at the University of Pennsylvania and an author of the study. "These data suggest that the Percepta test can potentially help physicians determine which patients are at low risk of cancer and can thus be followed with CT scans."

Through this study, along with the AEGIS I and II trials,[2] the Percepta test has been validated on more than 1000 patients at over 30 medical centers.

"We believe that, collectively, data from these three, rigorous clinical studies support the use of the Percepta Bronchial Genomic Classifier to help patients with suspicious lung nodules avoid unnecessary invasive procedures, while also reducing healthcare costs," said Bonnie Anderson, Veracyte's president and chief executive officer. "The need for improved lung cancer diagnosis has become even more critical as millions of Americans recently became eligible for annual CT screening through their insurers."

Lung cancer is the leading cause of cancer deaths in the United States, killing nearly 160,000 Americans each year. An estimated 250,000 patients currently undergo a bronchoscopy for suspected lung cancer each year in the United States, with approximately 40 percent producing inconclusive results. This outcome can lead to invasive procedures, such as transthoracic needle biopsy (TTNB) and surgical lung biopsy (SLB), which are risky and expensive.

About the Percepta Bronchial Genomic Classifier

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 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, Calif. The company began making the Percepta classifier available to a limited number of institutions around the United States in April 2015.

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 approximately 150 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 June 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] Whitney DH et al. Derivation of a bronchial genomic classifier for lung cancer in a prospective study of patients undergoing diagnostic bronchoscopy. *BMC Med Genomics*. 2015;8;18. Published online May 6, 2015.

[2] Silvestri GA et al. A bronchial genomic classifier for the diagnostic evaluation of lung cancer. *N Engl J Med* 2015; 373:243-251.