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New England Journal of Medicine Publishes Study Results Suggesting Veracyte's Percepta™ Bronchial Genomic Classifier Can Reduce Unnecessary Invasive Procedures in Lung Cancer Diagnosis

**-- Newest Data to Be Presented at American Thoracic Society 2015 International Conference --
-- Conference Call Scheduled for Monday, May 18, 8:00 a.m. ET/6:00 a.m. MT --**

SOUTH SAN FRANCISCO, Calif., May 17, 2015 /PRNewswire/ -- [Veracyte, Inc.](#) (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced online publication in the *New England Journal of Medicine* of results from two large, prospective, multicenter studies that assessed the clinical performance of the company's Percepta Bronchial Genomic Classifier in lung cancer diagnosis. Findings from the AEGIS I and AEGIS II trials demonstrate the ability of the genomic test to help patients safely avoid unnecessary invasive, risky procedures on suspicious lung nodules or lesions that were initially found on computed tomography (CT) scans.

The AEGIS trials involved 639 patients (298 in AEGIS I and 341 in AEGIS II) at 28 sites in the United States, Canada and Ireland who were undergoing bronchoscopy, a common nonsurgical procedure, to assess lung nodules for cancer. Specifically, among patients assessed clinically as having "intermediate" risk of malignancy who then had a non-diagnostic bronchoscopy, the Percepta test had a negative predictive value (NPV) of 91 percent, demonstrating the test's ability to reclassify these patients as "low risk" with a high degree of accuracy. The genomic test and the bronchoscopy had a combined sensitivity of 97 percent, compared to 75 percent for bronchoscopy alone. The genomic test's specificity was 47 percent in both studies. The sensitivity of the Percepta classifier alone and in combination with bronchoscopy was consistently high, regardless of nodule size and location, and cancer stage and type.

"These data suggest that the bronchial genomic classifier enables physicians to confidently identify patients who are at low probability for having lung cancer following an indeterminate bronchoscopy result," said senior author Avrum Spira, M.D., M.Sc., professor of medicine at Boston University School of Medicine and co-inventor of the genomic test. "Many of these patients can then be followed with CT scans, rather than undergoing harmful, invasive - and potentially unnecessary - follow-up procedures. The need for improved lung cancer diagnosis becomes increasingly acute given new screening programs that will expand the number of nodules found."

Beginning in early 2015, more than eight million Americans at high risk for lung cancer became eligible for annual screening with low-dose CT (LDCT) through new private-insurer and Medicare coverage requirements.

Lung nodules and lesions found on CT scans are often small and located at peripheral sites in the lung, making them hard to diagnose without invasive biopsies. Bronchoscopy is the safer, least-invasive diagnostic option, but often produces inconclusive results, leaving physicians with the dilemma of whether to subject patients to risky, invasive procedures or monitor them with the risk that they may in fact have cancer.

In the AEGIS trials, 43 percent of bronchoscopies were non-diagnostic for lung cancer, with 64 percent of patients undergoing invasive follow-up procedures, among which 35 percent of patients had benign nodules or lesions.

"These rigorous studies represent the largest evaluation to date of patients undergoing bronchoscopy, and establish the performance and utility of our Percepta Bronchial Genomic Classifier in lung cancer diagnosis," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "By helping to prevent unnecessary invasive diagnostic procedures, the Percepta test should provide very tangible benefits for patients and physicians, while removing costs from the healthcare system."

An estimated 250,000 patients currently undergo a bronchoscopy for suspected lung cancer each year in the United States, with approximately 40 percent producing non-diagnostic results. Such findings can lead to invasive procedures - transthoracic needle biopsy (TTNB) and surgical lung biopsy (SLB) - that are risky and expensive. TTNB, for example, has a 15-25 percent risk of collapsed lung; SLB is estimated to cost more than \$20,000.

The paper describing the AEGIS I and II study results, "A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer," appears in the May 17 online issue of the *New England Journal of Medicine*. Dr. Spira presented key data from the

studies in his keynote address at the American Thoracic Society 2015 International Conference, being held in Denver, CO.

Full data from the AEGIS II study will also be presented this week as part of an ATS mini-symposium, "Genomics and Cancer: Has it Borne Scientific and Clinical Fruit?":

Abstract Title: A Bronchial Airway Gene Expression Test for Lung Cancer Diagnosis is Validated in a Second Prospective Clinical Trial: Results of the AEGIS 2 Study (C99)

Presenter: Duncan Whitney, Ph.D.

Date/Time: Tuesday, May 19, 2:15 - 4:15 p.m. MT

Location: Room 605/607, Colorado Convention Center

A second ATS mini-symposium, "We Can Work It Out: Diagnosing and Differentiating Interstitial Lung Disease" will highlight data from a study of Veracyte's genomic test, in development, for idiopathic pulmonary fibrosis:

Abstract Title: Diagnosis of Idiopathic Pulmonary Fibrosis on Transbronchial Biopsies Using Machine Learning and High Dimensional Transcriptional Data (67185)

Presenter: Giulia C. Kennedy, Ph.D.

Date/Time: Wednesday, May 20, 1:30 - 3:30 p.m. MT

Location: Room 107/109/111/113, Colorado Convention Center

Conference Call on Monday, May 18, at 8:00 a.m. ET/6:00 a.m. MT

Ms. Anderson, Dr. Spira and members of Veracyte's management team will conduct a live conference call and webcast at 8:00 a.m. Eastern Time/6:00 a.m. Mountain Time to discuss the results of the AEGIS I and AEGIS II clinical validation studies.

The live webcast and subsequent replay may be accessed by visiting Veracyte's website at <http://investor.veracyte.com>. Alternatively, please call (855) 541-0980 (U.S.) or (970) 315-0440 (international) to listen to the live conference call. The conference ID number is 45232876. The webcast replay will be available on the company's website approximately two hours following completion of the call.

About the AEGIS Trials

The AEGIS I and AEGIS II studies evaluated 639 current or former smokers undergoing bronchoscopy for suspected lung cancer. In addition to obtaining standard biopsy samples from the lung nodule or lesion, researchers collected samples from the more-accessible mainstem bronchus for evaluation using the Percepta test. Results of the classifier were not reported to physicians or patients. Patients were then followed until a diagnosis was established or 12 months post bronchoscopy. A lung cancer diagnosis was established either through bronchoscopy or invasive procedures; a benign diagnosis was made through these same procedures or following stable imaging studies.

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 a non-diagnostic 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, 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 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 our planned entry into the pulmonology market, our beliefs regarding the benefits and attributes of our Percepta test, our expectations regarding revenue from the Percepta test, 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 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 test; 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 our Percepta Bronchial Genomic Classifier; our ability to obtain reimbursement for the Percepta test; 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 Annual Report on Form 10-K for the year ended December 31, 2014. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

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