



February 29, 2016

## **Veracyte Announces Publication of Data Confirming Analytical Verification of Percepta® Bronchial Genomic Classifier**

SOUTH SAN FRANCISCO, Calif., Feb. 29, 2016 /PRNewswire/ -- [Veracyte, Inc.](#) (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced that data confirming the analytical performance of the company's Percepta Bronchial Genomic Classifier have been published online in the journal [BMC Cancer](#). The findings add to the growing body of evidence, including previously reported clinical validity and clinical utility data, supporting the use of the Percepta classifier to help resolve ambiguity in lung cancer diagnosis and thus reduce the unnecessary, invasive procedures that can result.

"The analytical verification data published today reinforce the quality and scientific rigor behind our Percepta Bronchial Genomic Classifier," said Bonnie Anderson, Veracyte's president and chief executive officer. "These new findings should help advance our efforts to secure reimbursement for and to subsequently expand commercialization of the test, which we believe will transform lung cancer diagnosis to benefit patients, physicians and payers."

Veracyte researchers used industry-defined evaluation parameters for novel genomic tests<sup>1</sup> to study the analytical performance of the Percepta classifier. The entire Percepta testing process was evaluated, from sample collection through classification, including specimen stability during collection, shipment and storage, and test reproducibility.

The data published today show that the Percepta classifier demonstrates strong accuracy, specificity, sensitivity and reproducibility under a range of conditions and variables. These include high stability of specimens during collection and storage as well as consistent test performance despite common sample variations, such as RNA quantity and potential blood and DNA contamination, that the classifier is likely to encounter in clinical use. The study also showed that the Percepta classifier results are reproducible across operators, processing runs, reagent lots and laboratories.

### **About Percepta**

The Percepta Bronchial Genomic Classifier is used to identify patients with lung nodules who are at low risk of cancer following an inconclusive bronchoscopy result, thereby enabling these patients to be safely monitored with CT scans in lieu of invasive diagnostic procedures. The 23-gene molecular classifier has been clinically proven in three multicenter studies with greater than 1,000 patients enrolled across more than 30 medical centers. 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 the likelihood that a lung nodule or lesion is cancerous 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](http://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.

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

1. Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group; Centers for Disease Control ACCE Project

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/veracyte-announces-publication-of-data-confirming-analytical-verification-of-percepta-bronchial-genomic-classifier-300227904.html>

SOURCE Veracyte

News Provided by Acquire Media