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## Veracyte Receives Regulatory Authorization to Offer Percepta™ Bronchial Genomic Classifier for Patients in New York State

## -- Genomic Test Helps Resolve Ambiguity in Lung Cancer Diagnosis --

SOUTH SAN FRANCISCO, Calif., Jan. 28, 2016 /PRNewswire/ --Â <u>Veracyte, Inc.</u> (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced that it has received regulatory authorization from the New York State Department of Health to offer the Percepta<sup>TM</sup> Bronchial Genomic Classifier for patients in the state. The genomic test, commercially introduced in April 2015, is used to help patients avoid unnecessary invasive, risky and costly procedures to assess potentially cancerous lung nodules that were initially found on CT scans.

"We are delighted that the Percepta Bronchial Genomic Classifier will now be available to physicians and their patients in New York State," said Bonnie Anderson, Veracyte's president and chief executive officer. "This significant milestone underscores the clinical need for and strength of the validation data supporting our test. We look forward to offering the Percepta test in New York State as we continue its initial rollout to select institutions around the country."

The Percepta Bronchial Genomic Classifier comprises a 23-gene test that uses proprietary technology to identify patients with lung nodules or lesions who are at low risk of cancer following an inconclusive bronchoscopy result, so that they may be monitored with CT scans rather than undergoing invasive diagnostic procedures. The test's performance has been proven in prospective, multicenter studies, the results of which were published in <u>The New England Journal of Medicine</u>.

Lung cancer is the leading cancer killer in the United States, where more than 220,000 new cases and nearly 160,000 deaths were expected in 2015. Lung nodules found on CT scans are often difficult to diagnose without invasive biopsies, which are risky, costly and often unnecessary. Bronchoscopy provides a less-invasive alternative, but among the 250,000 patients who undergo bronchoscopy each year for lung nodule evaluation, approximately 40 percent receive inconclusive results, meaning that cancer could not be ruled out. This diagnostic challenge is expected to increase, given that an estimated eight million Americans became eligible for annual lung cancer screening in 2015 through new insurance-coverage requirements.

The Percepta test may now be offered to patients with inconclusive bronchoscopy results under Veracyte's current laboratory permit with the New York State Department of Health, while the agency completes its final review.

## **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; A 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;Â 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.

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