October 26, 2016

New Data Show that Use of Percepta® Bronchial Genomic Classifier Reduces Surgeries and Other Costly Procedures in Lung Cancer Screening and Diagnosis

-- Findings from Prospective, Multicenter Study Presented at CHEST Annual Meeting 2016 --

SOUTH SAN FRANCISCO, Calif., Oct. 26, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT) today announced new data from a prospective, multicenter clinical utility study showing that use of the Percepta Bronchial Genomic Classifier to resolve inconclusive diagnostic results in patients undergoing evaluation for suspected lung cancer led to a significant reduction in surgeries and other costly, invasive procedures. The findings, presented at the CHEST Annual Meeting 2016 being held this week in Los Angeles, demonstrate the genomic classifier's ability to improve the clinical efficacy of lung cancer screening and diagnosis without the need for surgery.

The new study comprised 230 patients with lung nodules or lesions found on CT scans who received an inconclusive result on their bronchoscopy - a minimally invasive procedure used to evaluate lung nodules - and whose nodule samples were then tested with the Percepta classifier. Among patients with a low or intermediate pre-test risk of malignancy (based on clinical factors and smoking history), use of the Percepta classifier resulted in a 33 percent decrease in surgical procedures when the genomic test reclassified them as "very low risk" or "low risk" for cancer. This is compared to how physicians previously reported that they would manage such patients without the genomic test results. Use of the test also led to a 28 percent reduction in the frequency of follow-up CT scans. The interim findings are from an ongoing clinical utility study for the genomic test, which involves over 40 academic, community and U.S. Department of Veterans Affairs sites around the country.

"Diagnosing lung nodules is often challenging, due to their small size or hard-to-reach location," said D. Kyle Hogarth, M.D., pulmonologist and associate professor of medicine at The University of Chicago Medicine, who shared the findings in a poster presentation. "While lung cancer screening offers new opportunities to save lives through early detection, it increases the risk of finding nodules that are not clearly benign or cancerous, even after a bronchoscopy. This can lead to risky and expensive surgery, which often turns out to be unnecessary. Our new findings confirm that use of the Percepta classifier helps reduce surgeries and other costly procedures by giving physicians clearer answers earlier."

The new study results underscored the challenge associated with lung cancer diagnosis. The researchers found that bronchoscopy alone was able to provide an actionable diagnosis in only 31 percent of patients undergoing a work-up for potential lung cancer.

Lung cancer kills nearly 160,000 Americans each year - more than the next three leading cancers combined. In 2015, more than eight million Americans became eligible through Medicare and private insurance for annual lung cancer screening with low-dose computed tomography (LDCT) in an effort to find cancers earlier, when they are more treatable.

Additional clinical utility data presented at the CHEST 2016 meeting by Ryan Van Wert, M.D. of the Stanford School of Medicine suggest that the Percepta classifier would prompt a significant reduction (from 57 percent to 18 percent) in invasive procedure recommendations by physicians, compared to when no genomic test results are available following an inconclusive bronchoscopy. Researchers found that physicians were also likely to reduce their invasive procedure recommendations, regardless of setting (academic vs. community-based), number of bronchoscopies performed, geography or other factors. These data are based on a survey of 202 physicians.

"These two studies provide compelling evidence that use of the Percepta Bronchial Genomic Classifier is changing care for lung nodule patients, enabling them to avoid the operating room in their effort to get a diagnosis," said Bonnie Anderson, Veracyte's president and chief executive officer. "We believe these clinical utility findings will support expanded coverage and reimbursement for the Percepta classifier, making it more widely accessible to lung nodule patients, including the eight million Americans now eligible for lung cancer screening."

Three Medicare Administrative Contractors have recently issued draft local coverage policies that, when finalized, will enable access to the Percepta classifier for more than half of the Medicare beneficiaries across the United States.

About Percepta
The Percepta Bronchial Genomic Classifier is designed to improve the accuracy of lung cancer screening and diagnosis without the need for invasive surgery. Clinical validation data from two prospective, multicenter studies were published in July 2015 in *The New England Journal of Medicine* and demonstrate that the Percepta test identified patients at low risk of cancer with a high degree of accuracy (negative predictive value of 91 percent). The test also increased the accuracy of bronchoscopy (97 percent combined sensitivity for cancer versus 75 percent using bronchoscopy alone). The 23-gene classifier identifies patients with lung nodules who are at low risk of cancer following an inconclusive bronchoscopy result, making it possible to monitor these patients with CT scans in lieu of invasive diagnostic procedures. 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 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 classifier is performed at Veracyte's CLIA-certified laboratory in South San Francisco, California. For more information, view the Percepta video.

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 185 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 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer, which has already received draft Medicare coverage. In October 2016, Veracyte launched its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of 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 the benefits of Percepta to patients, physicians and payers, our belief that the use of the Percepta classifier helps reduce surgery and other costly procedures by giving physicians clearer answers earlier, our belief that Percepta is changing care for lung nodule patients, the limitations of current diagnostic procedures, and our belief that the clinical utility findings will support expanded coverage and reimbursement for our test, and the parties who may benefit from such expanded coverage and reimbursement. 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: the ability of Percepta to change physicians' practices; our ability to increase usage of and reimbursement for Percepta; the applicability of clinical results to actual outcomes; the finalization of draft coverage policies; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; the size of the market opportunity for Percepta; our ability to successfully achieve adoption of and adequate reimbursement for Percepta; the amount by which use of our products are able to reduce invasive procedures and reduce healthcare costs; the occurrence and outcomes of clinical studies; the timing and publication of clinical study results; 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, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/new-data-show-that-use-of-percepta-bronchial-genomic-classifier-reduces-surgeries-and-other-costly-procedures-in-lung-cancer-screening-and-diagnosis-300351932.html

SOURCE Veracyte