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# Veracyte Achieves Major Medicare Coverage Milestone for the Percepta® Classifier to Improve Lung Cancer Diagnosis

## Conference Call and Webcast Today at 11:00 a.m. Eastern

SOUTH SAN FRANCISCO, Calif., Sept. 8, 2016 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT) today announced that Noridian Healthcare Solutions, the nation's largest Medicare Administrative Contractor (MAC), has issued a draft local coverage determination (LCD) for the Percepta Bronchial Genomic Classifier. When finalized, this LCD will enable coverage for over 30 million - or more than half - of the Medicare beneficiaries in the United States. The Percepta classifier is the first genomic test for use in lung cancer diagnosis to achieve this important Medicare coverage milestone. The test is supported by multiple published studies demonstrating its ability to make lung cancer screening and diagnosis more accurate and safe by reducing unnecessary surgeries on suspicious lung nodules found on computed tomography (CT) scans.

The draft local coverage determination posted online by Noridian establishes the Percepta coverage policy for Medicare beneficiaries in the MAC's 14-state jurisdiction and provides coverage for the more than 17 million Medicare Advantage members nationwide. Noridian's jurisdiction includes California, where Veracyte performs and bills for the molecular test. The LCD specifies coverage for the use of Percepta in patients with an inconclusive bronchoscopy to identify those who may be followed with CT surveillance in lieu of further invasive biopsies or surgery. Under CMS rules, the draft LCD is open to a 45-day public comment period. The company anticipates the final LCD will be issued and go into effect on or about January 1, 2017.

"This is a tremendous achievement for the company," said Bonnie Anderson, president and chief executive officer of Veracyte. "The strength of the evidence supporting Percepta met a high bar for coverage established by the Medicare MolDx Program and serves as a solid foundation for commercial expansion in 2017. We expect that the other MACs that participate in the Palmetto GBA-administered MolDx Program and typically follow its policies will also issue local coverage determinations for Percepta in the future."

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 insurers for annual lung cancer screening with low-dose CT in an effort to find cancers earlier, when they are more treatable. Veracyte estimates that over 50 percent of these individuals are covered by Medicare.

"Lung cancer screening has the potential to save lives," said Avrum Spira, M.D., M.Sc., professor of medicine at Boston University School of Medicine and co-inventor of the genomic test. "One of the biggest challenges in lung cancer screening, however, has been the risk of finding lung nodules that are not clearly benign or cancerous. While bronchoscopy is often the initial diagnostic tool used in this setting, it is frequently inconclusive. This often leads to costly and potentially risky surgeries on nodules that ultimately prove to be benign."

The Percepta test is run following an inconclusive result from bronchoscopy - a minimally invasive procedure that is commonly used to evaluate suspicious lung nodules and lesions found on CT. 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). Published clinical utility data suggest that use of the Percepta test could reduce unnecessary surgeries and other invasive procedures by 50 percent. Veracyte estimates the U.S. market opportunity for Percepta to be $425 million to $525 million today and expects the market to increase in size as lung cancer screening expands.

### About Percepta

The Percepta Bronchial Genomic Classifier is designed to improve the accuracy and safety of lung cancer screening and diagnosis. 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.

**Conference Call today at 11:00 a.m. Eastern**

Ms. Anderson and members of Veracyte's management team will conduct a live conference call and webcast today at 11:00 a.m. Eastern to discuss the draft Medicare coverage for the Percepta classifier, the clinical and market landscape for the test and the company's commercialization plans.

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 70727748. The webcast replay will be available on the company's website approximately two hours following completion of the call.

**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 180 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. In the fourth quarter of 2016, Veracyte plans to launch its second pulmonology product, the Envisia™ 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 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 2016 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; the size of the market opportunity for our Percepta Bronchial Genomic Classifier; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; the amount the use of the Percepta Bronchial Genomic Classifier is able to reduce invasive procedures and reduce healthcare costs; 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 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 March 31, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.