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Veracyte Initiates Launch of Percepta™ Bronchial Genomic Classifier to Improve Lung Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif., April 16, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a molecular diagnostic company pioneering the field of molecular cytology, today announced the launch of its Percepta™ Bronchial Genomic Classifie a new genomic test to resolve ambiguity in lung cancer diagnosis. The company will soon begin testing patient samples in its CLIA-certified laboratory, with the Percepta test now available to a limited number of institutions around the country.

The Percepta test is designed to reduce the number of invasive biopsies and other procedures that can follow when suspicious lung nodules are found on computerized tomography (CT) scans. The test is used when results from a bronchoscopy - a common nonsurgical procedure to evaluate lung nodules - are non-diagnostic, meaning that cancer cannot be ruled out. Data from a prospective, multicenter clinical validation study previously demonstrated the Percepta test's ability to identify patients whose lung nodules are at low risk of malignancy so that they can be monitored with CT scans in lieu of invasive diagnostic procedures.

"Our Percepta test can help patients avoid unnecessary, potentially risky procedures while simultaneously reducing the growing cost burden associated with lung cancer diagnosis," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "We believe the clinical and public-health need for the Percepta test becomes even greater as more patients become eligible for new lung cancer screening programs."

Ms. Anderson noted that, 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.

"Bronchoscopy is attractive to clinicians and patients because it offers a nonsurgical method for diagnosing suspicious lung nodules. However, given the difficulty in accessing small peripheral nodules, it often produces non-diagnostic results, leaving clinicians with the dilemma of whether to subject patients to invasive and potentially unnecessary diagnostic procedures or just monitor them with CT scans, with the risk that they may have cancer," said Avrum Spira, MD, M.Sc., professor of medicine at Boston University and co-developer of the genomic test. "The Percepta test can help determine a lung nodule's likelihood of cancer, without the need to sample the nodule directly, which should provide very tangible benefits to patients, medical professionals and the healthcare system."

Veracyte's test comprises a 23-gene molecular classifier that uses proprietary "field of injury" technology to detect molecular changes that occur in the epithelial cells lining the lung's respiratory tract in response to smoking - the cause of 85-90 percent of lung cancers. These changes can be detected in cells obtained from standard cytology brushings taken during bronchoscopy from the proximal airway, and indicate the presence of malignancy or disease processes from distant sites in the lung.

An estimated 250,000 patients currently undergo a bronchoscopy each year in the U.S., with approximately 40 percent producing non-diagnostic results. These numbers are expected to increase significantly with the new insurance coverage requirements for annual CT screening. Veracyte noted that it does not expect meaningful revenue from the Percepta test until 2017.

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. Since launching its Afirma solution in 2011, Veracyte estimates it has helped approximately 15,000 patients with thyroid nodules avoid unnecessary surgery, reducing healthcare costs by millions of dollars. The Afirma test is recommended in leading practice guidelines and is covered for 145 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 introduce and 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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