OncoCyte Reports Successful Results of Lung Cancer Diagnostic Test Study; Targets 2017 Product Launch to Address $4 Billion-plus Market

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Data from the Study Exceed Levels Believed Necessary for a Commercially Successful Test

Conference Call Scheduled for Today at 4:30 PM ET

ALAMEDA, Calif., March 06, 2017 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE MKT:OCX), a developer of novel, non-invasive blood based tests to aid in the early detection of cancer, today reported the successful completion of a critical step in the development of its lung cancer diagnostic test. While the key performance metrics of its diagnostic cannot be revealed until they are presented at the American Thoracic Society Meeting in May, the company has locked its prediction algorithm and intends to move to the Clinical Validation Phase of development—the last phase before commercial launch. The data from the study exceed levels OncoCyte believes necessary for a commercially successful test and the Company is moving forward with plans to launch the lung cancer diagnostic test during the second half of 2017.

OncoCyte's algorithm confirmed the results of an earlier study by The Wistar Institute of Anatomy and Biology, which reported its results at the CHEST 2016 Annual Meeting in October 2016. The Area Under the Curve (AUC) in Wistar's study was 0.82 with a sensitivity of 90% and specificity of 62%. OncoCyte's study results were consistent with Wistar's.

The AUC of a test is a measure that combines sensitivity and specificity to express its total accuracy, with 1.0 being perfect accuracy and 0.50 being a random result. Sensitivity and specificity are statistical measures of test performance, with sensitivity measuring the percentage of malignant nodules that are identified correctly by the test and specificity measuring the percentage of benign nodules correctly identified.

OncoCyte's assessment of the market leads management to believe that it is positioned to be the first company to provide a highly accurate non-invasive confirmatory blood test for lung cancer. Based on published sources, Lung RADS guidelines and NLST (National Lung Screening Trial) data, the Company estimates that approximately 1.4 million patients annually in the U.S. could benefit from its test. Assuming this number of patients and the Company's currently planned pricing for such a test, the total addressable market could potentially exceed $4 billion. OncoCyte believes that its blood based lung cancer test can provide Medicare and private insurance companies with significant savings if the price of its product is about 20 to 25 percent of the cost of an invasive lung biopsy, which according to recent Medicare estimates averages approximately $15,000. Potential revenue to OncoCyte will depend in large measure on the test's market penetration and on approved reimbursement by Medicare and health insurers.

The results of OncoCyte's study will be presented at The American Thoracic Society conference in May by its lead author, Dr. Anil Vachani, Associate Professor of Medicine at the Hospital of the University of Pennsylvania, located in Philadelphia, PA. "If the assay continues to perform at these levels, it could create a significant improvement in the standard of care in lung nodule management. Current practice can result in patients undergoing avoidable invasive procedures, which a diagnostic test of this type could help to reduce significantly, while also lowering the cost to determine the presence of lung cancer," said Dr. Vachani.

OncoCyte's study utilized Wistar's biomarker panel, which has been exclusively licensed to OncoCyte. The study developed and tested OncoCyte's proprietary algorithm, using approximately 300 samples collected from patients at 26 community based, academic and government sites across the United States. OncoCyte developed its algorithm by combining data from the top mRNA biomarkers with clinical data such as nodule size. The algorithm was self-tested via a six-fold internal cross-validation on the samples. Cross-validation is a statistical method used to develop and estimate the performance of an algorithm.

The samples were collected from patients with nodules ranging in size from five to thirty millimeters, the size range presenting the greatest diagnostic challenge to clinicians. For patients with these size nodules, physicians must weigh the risk of cancer against the risks posed by costly and potentially dangerous invasive biopsies to confirm whether the nodules are malignant or benign.

Because of the study's successful results, OncoCyte also announced that it will begin ramping-up its commercial capabilities in anticipation of the potential launch of the test. OncoCyte will initiate a Clinical Validation Phase for this diagnostic. During this phase, the company will continue to carry out analytical validation studies to refine its operational stage laboratory processes and will apply for certification of its CLIA diagnostic testing lab. Upon CLIA certification, OncoCyte will conduct a small CLIA lab validation study to demonstrate that the full assay system utilized in the CLIA lab provides the same results on clinical samples as those obtained in the R&D lab. OncoCyte then will begin a clinical validation study using the finalized algorithm and operational procedures on a new set of at least 300 blinded prospectively collected samples to confirm whether the sensitivity and specificity of the test remain within commercial parameters in a CLIA operational setting. Assuming successful completion of these steps, OncoCyte anticipates launching the test commercially in the second half of 2017.

"We are very excited about the successful results of our study," commented William Annett, President and Chief Executive Officer. "Our goal is to have the first commercial blood test that can help physicians to better manage patients presenting with lung nodules, and to avoid a significant number of risky and costly biopsies."

Conference Call

The Company will host a conference call on Monday, March 6, 2017 at 4:30 p.m. ET / 1:30 p.m. PT to discuss the study results as well as its 2016 financial results. The dial-in number in the U.S./Canada is 888-427-9421, for international participants the number is 719-325-2450. For all callers, refer to Conference ID 9994065. To access the live webcast, go to the investor relations section on the company's website, http://investors.oncocyte.com/events-and-presentations.

A replay of the conference call will be available for seven business days beginning about two hours after the conclusion of the live call, by calling 888-203-1112-toll-free (from U.S./Canada); international callers dial +1 719-457-0820. Use the Conference ID 9994065. Additionally, the archived webcast will be available http://investors.oncocyte.com/events-and-presentations.

About OncoCyte Corporation

OncoCyte is focused on the development and commercialization of novel, non-invasive blood and urine ("liquid biopsy") diagnostic tests for the early detection of cancer to improve health outcomes through earlier diagnoses, to reduce the cost of care through the avoidance of more costly diagnostic procedures, including invasive biopsy and cystoscopic procedures, and to improve the quality of life for cancer patients. While current biopsy tests use invasive surgical procedures to provide tissue samples in order to determine if a tumor is benign or malignant, OncoCyte is developing a next generation of diagnostic tests that will be based on liquid biopsies using blood or urine samples. OncoCyte's pipeline products are intended to be confirmatory diagnostics for detecting lung, breast and bladder cancer. OncoCyte's diagnostic tests are being developed using proprietary sets of genetic and protein markers that differentially express in specific types of cancer.

Forward Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates" and similar expressions) should also be considered to be forward-looking statements. These statements include those pertaining to the implementation and results of our validation study and other studies, commercialization plans, future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for OncoCyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the need and ability to obtain future capital, and maintenance of intellectual property rights, and the need to obtain third party reimbursement for patient's use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of OncoCyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in OncoCyte's Securities and Exchange Commission filings. OncoCyte disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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