OncoCyte Presents Positive Lung Cancer Blood Test Data at American Thoracic Society

May 22, 2017

- Continues Plans to Commercialize Lung Cancer Diagnostic Test in 2017 -

- Conference Call Today at 4:30 PM Eastern Daylight Time -

ALAMEDA, Calif., May 22, 2017 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE MKT:OCX), a developer of novel, non-invasive blood-based liquid biopsy tests for the early detection of cancer, today reported positive new results in its development of a highly-accurate blood-based lung cancer diagnostic. Data from a multi-site study further validate the test's commercial potential and support OncoCyte's plans to commercialize its first product, a confirmatory test for lung cancer, later this year. If successful, OncoCyte's test could eventually replace a high percentage of invasive, risky, and expensive lung biopsies with simple blood tests, improving outcomes for patients while also capturing significant cost savings for the U.S. healthcare system. The results were reported today in a poster presentation by Dr. Anil Vachani, at the American Thoracic Society 2017 International Conference in Washington, D.C.

A PDF accompanying this release is available at
http://www.globenewswire.com/NewsRoom/AttachmentNg/b3ce3fea-2aa3-4f97-ae67-54a3905094df

Dr. Vachani, Associate Professor of Medicine at the Hospital of the University of Pennsylvania, reported that in a study of 299 samples collected prospectively from 29 U.S. sites, the optimized final predictive algorithm demonstrated sensitivity of 95%, specificity of 73%, and Area Under the Curve (AUC) of 0.92.

Results from this study of the optimized final predictive algorithm confirmed the data from a previous 610-sample study that was reported in October 2016 by the Wistar Institute (OncoCyte's research partner) at the American College of Chest Physicians CHEST 2016 Annual Meeting. The development of the lung cancer diagnostic test is a result of nearly ten years of research and the analysis of thousands of samples by Wistar, followed by improvement from OncoCyte's current study.

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. The AUC of a test is a measure of overall global accuracy that combines sensitivity and specificity, with 1.0 being perfect accuracy and 0.50 being a random result. The reported score of 0.92 means that 92% of samples were correctly identified.

OncoCyte believes the results reported today significantly exceed levels necessary for a commercially successful test.

“The robust lung cancer diagnostic test study data suggest that OncoCyte’s potential lung cancer confirmatory diagnostic could result in a major reduction in the number of risky and costly lung biopsies performed annually in the U.S.,” said Dr. Vachani. “I believe this test could represent a fundamental advancement in the more accurate diagnosis of suspicious lung nodules by allowing physicians to determine those who need biopsies as opposed to those who need follow-up imaging.”

William Annett, President and Chief Executive Officer, commented, “Based on the predictive level of our new algorithm, we believe we are well positioned to be the first company to provide a novel, highly accurate test to a patient market that could reach $4 billion annually, depending on market penetration and reimbursable pricing. We believe we will have the first-mover advantage that could be sustained for at least several years.”

The Company’s health economics research indicates that its lung cancer diagnostic test could mitigate the need for hundreds of thousands of unnecessary lung biopsies. Because lung biopsies have significant safety risks, these unnecessary lung biopsies could result in thousands of consequent hospitalizations and deaths annually. Reducing the number of these biopsies therefore would also reduce their cost burden to private health insurers and Medicare by billions of dollars. OncoCyte’s surveys of physicians and payors have consistently indicated a strong desire for a test that could reduce the number of lung biopsies, and the expectation is that such a test would be adopted quickly by both prescribers and payors. 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.

Development and Commercialization Path

For the study presented at the ATS conference, OncoCyte and its investigative partners first created an algorithm that roughly matched the Wistar study results using all 200 biomarkers included in the Wistar algorithm, and OncoCyte then optimized the algorithm’s performance by using only those biomarkers with the highest predictive ability. In addition, the Company’s new algorithm also factors in size of the lung nodule.

OncoCyte has now locked the algorithm of its test and is preparing to commercialize it. During the next few months, the Company plans to complete analytical validation studies and anticipates CLIA certification of its testing laboratory in mid-2017. 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 its R&D lab.

Upon CLIA certification, OncoCyte will carry out a final clinical validation study using the locked algorithm and finalized operational procedures on a new set of blinded prospectively collected samples in order to confirm that the sensitivity and specificity of the test remains within commercial parameters in the CLIA operational setting. This final study is not required before commercialization. However, the Company believes that the results of this study should enhance the probability of rapid adoption as the new standard of care for confirming diagnoses of lung cancer. Assuming successful completion of these steps, OncoCyte anticipates launching the test in the second half of 2017. Subsequent to the launch, OncoCyte plans a continued program of clinical utility and health economics studies to support adoption of the test by the medical community, and reimbursement from third party payers such as Medicare and health insurers. OncoCyte also plans to conduct additional biomarker research and clinical studies to develop improved versions of its test that could have even higher accuracy or extend the intended use to additional patient profiles.

About the Lung Cancer Diagnostic Test Study and Poster Presentation

OncoCyte's lung cancer diagnostic 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 29 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 samples were collected from patients with nodules ranging in size from five to 30 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.

The original abstract was submitted in December 2016 for presentation at the American Thoracic Society 2017 International Conference, and was based on the analysis of 106 samples completed at that time. Subsequent to the submission of that abstract, which was published in the ATS conference guide, the analysis was completed on the full set of 299 samples and the results of that analysis were presented in the final poster, which is attached to this release.

Conference Call

OncoCyte will host a conference call today at 4:30 p.m. EDT / 1:30 p.m. PDT to discuss the study results.

The dial-in number in the U.S./Canada is 888-359-3610, for international participants the number is +1 719-457-2648. For all callers, refer to Conference ID 7395442. 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 7395442. Additionally, the archived webcast will be available at 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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