OncoCyte Analytical Validation Study of its Lung Cancer Diagnostic Test Confirms Previously Published Results

Jul 24, 2017

- Abstract to Present Complete Study Findings Submitted to a Scientific Conference -

- Final Stage of Development Commences-

ALAMEDA, Calif., July 24, 2017 (GLOBE NEWSWIRE) -- **OncoCyte Corporation** (NYSE MKT:OCX), a developer of novel, non-invasive blood-based liquid biopsy tests to assist in the early detection of cancer, announced today that it has successfully completed the Analytical Validation study of its liquid biopsy lung cancer diagnostic test. The results are consistent with the data reported in May at the American Thoracic Society 2017 International Conference (ATS), which demonstrated sensitivity of 95%, specificity of 73%, and Area Under the Curve (AUC) of 0.92. (An AUC of .92 means that 92% of samples were correctly identified.) The final development step before the commercial launch of the lung cancer diagnostic test will be Clinical Validation, which has commenced with a planned completion in the fourth quarter of this year. If Clinical Validation is successful and OncoCyte's clinical laboratory receives CLIA certification, then the lung cancer test will be the only commercially available product in what the Company estimates is an up to $4.7 billion annual market opportunity in the U.S.

Analytical Validation

The studies required for Analytical Validation have been established in the CLSI (Clinical Lab Standards Institute) Guidelines. These guidelines cover the testing for such matters as limits of quantitation, precision, reproducibility, and interfering substances. OncoCyte has completed all of these studies successfully.

The new Analytical Validation data supports expectations that the test's performance will continue to be robust. The completion of the study establishes the performance characteristics of OncoCyte's lung cancer diagnostic test and, if the Clinical Validation studies are successful, will allow for industrial scale operations under real world conditions. The Company has submitted an abstract to present the data at a scientific conference this year.

"The data seen in this study ensure reliable and actionable liquid biopsy test results that physicians can use in clinical practice to help patients make more informed treatment decisions," stated Lyndal Hesterberg, Ph.D., Senior Vice President, Research and Development. "The successful completion of the Analytical Validation study is an important milestone as we progress toward commercialization of the test in the second half of 2017 following CLIA certification of the Company's laboratory and completion of the Clinical Validation stage."

"We estimate that our lung cancer confirmatory diagnostic could result in a substantial reduction in the number of unnecessary, expensive lung biopsies performed annually in the U.S., thereby representing a fundamental advancement in the more accurate diagnosis of suspicious lung nodules by allowing physicians to determine which patients need biopsies versus those who may only need follow-up imaging," said William Annett, President and Chief Executive Officer. "We estimate that approximately 1.4 million patients annually in the U.S. could benefit from the test. Depending on market penetration and reimbursable pricing, we believe this could translate into a market opportunity of up to $4.7 billion annually."

Clinical Validation Stage Underway

The final stage of development following the now completed Analytical Validation Study is Clinical Validation. This stage consists of two distinct sets of studies that will be carried out in OncoCyte's new clinical laboratory. The first step is CLIA Lab Validation. In this study, OncoCyte will assay approximately 120 samples previously tested in the 299-patient study presented at the ATS meeting, with the goal of demonstrating that OncoCyte's new clinical laboratory provides the same results on clinical samples as those obtained in OncoCyte's R&D lab. This study has now begun.

On completion of the CLIA Lab Validation study the second step will be two CLIA Lab Clinical Validation studies. In these studies, OncoCyte will perform assays on blinded prospectively collected samples to assess the performance of the full diagnostic system against clinically confirmed diagnoses. OncoCyte will perform Clinical Validation on two sets of samples. The first study will consist of approximately 300 samples, and if the results of the study are consistent with results to date OncoCyte will launch its liquid biopsy lung cancer diagnostic test. All of the samples required for this first study have now been collected.

The second study will be conducted post-launch and on approximately 200 additional samples to provide additional data to increase the likelihood that physicians will adopt the test and that insurance companies and Medicare will provide reimbursement coverage for the test.

CLIA Certification

OncoCyte's clinical laboratory must receive Clinical Laboratory Improvement Amendment (CLIA) certification from the state of California. The Company's complete application for CLIA certification was submitted in March 2017 to the California Department of Public Health and is now under active review. The Company expects to receive CLIA certification during the second half of 2017.

Diagnostic Test Accuracy

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 score of 0.92 reported at the recent ATS meeting means that 92% of samples were correctly identified.

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) are forward-looking statements. These statements include those pertaining to the implementation and results of our 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.

Investor Contact:

EVC Group, Inc.
Matt Haines / Michael Polyviou
917-733-9297/212-850-5600
mhaines@evcgroup.com/mployviou@evcgroup.com

Financial Media Contact:

GIBSON Communications, LLC
Tom Gibson
201-476-0322
tom@tomgibsoncommunications.com

Source: OncoCyte Corporation

Powered by SITECORE