OncoCyte Reports Positive Analytical Validation Study Results of DetermaVu™ Lung Cancer Diagnostic Test

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DetermaVu™ Launch On-Track for Fourth Quarter 2017

ALAMEDA, Calif., Sept. 18, 2017 (GLOBE NEWSWIRE) -- **OncoCyte Corporation** (NYSE American:OCX), a developer of novel, non-invasive blood-based liquid biopsy tests to assist in the early detection of cancer, announced today positive final results from the Analytical Validation Study of its liquid biopsy lung cancer diagnostic test, DetermaVU™. The data were presented by Philip McQuary Ph.D., Director of Product Development, OncoCyte Corporation, at the International Association for the Study of Lung Cancer (IASLC), in Chicago.

The accuracy results of the Analytical Validation Study reported today demonstrate sensitivity of 94.4%, specificity of 67.5% and Area Under the Curve (AUC) of 0.93, which means that 93 percent of the samples tested during the Analytical Validation were correctly diagnosed. These data are consistent with the data reported in May at the American Thoracic Society 2017 International Conference.

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 0.93 reported at the recent IASLC meeting means that 93 percent of the samples were correctly identified.

The next step in the process leading to commercial launch of DetermaVu is a CLIA Validation study, which is now underway and expected to be completed in the third quarter of this year. If the CLIA Validation study is successful, the final step will be a Clinical Validation study, which is expected to be completed in the fourth quarter of this year. If the Clinical Validation study is successful, OncoCyte plans to launch DetermaVu. OncoCyte believes that at launch DetermaVu will be the only commercially available liquid biopsy lung cancer product in what the Company estimates is an up to $4.7 billion annual market opportunity in the U.S.

“The new data seen in the Analytical Validation Study provide further evidence of the reliability of the DetermaVu assay system in identifying cancerous nodules,” stated Lyndal Hesterberg, Ph.D., Senior Vice President, Research and Development. “These data give support our belief that physicians will be able to use DetermaVu with confidence in their clinical practice to help patients make more informed treatment decisions.”

William Annett, President and Chief Executive Officer, commented, “We are excited that the results reported at the IASLC conference confirm the positive data reported in May at the American Thoracic

Society meeting. If our upcoming Clinical Validation study is successful, we intend to commercialize DetermaVu in the fourth quarter of 2017."

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 support 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.

OncoCyte believes that DetermaVu 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. The Company estimates that approximately 1.4 million patients annually in the U.S. could benefit from the test. Depending on market penetration and reimbursable pricing, 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 CLIA approved 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 is underway.

Upon successful 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. If the results of the study are consistent with results to date, OncoCyte will launch DetermaVu.

The second study will be conducted post-launch 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.

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 research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future 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 patients' use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly as such statements 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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