OncoCyte Receives CLIA Certification for its Cancer Diagnostics Laboratory

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ALAMEDA, Calif., Sept. 07, 2017 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE American:OCX), a developer of novel, non-invasive tests for the early detection of cancer, today announced that its clinical laboratory facility located in Alameda, California, has received Clinical Laboratory Improvements Amendments (CLIA) certification of registration from the Centers for Medicare and Medicaid Services (CMS). In addition, OncoCyte's laboratory has passed inspection by the California Department of Public Health and is now fully licensed and operational.

OncoCyte plans to use its CLIA-certified laboratory to commercialize proprietary cancer diagnostic tests. The Company expects to launch its first assay, DetermaVu™, a confirmatory lung cancer diagnostic, in the fourth quarter of 2017, assuming successful completion of CLIA Validation and Clinical Validation studies. OncoCyte estimates that a $4.7 billion annual market could develop in the U.S. for confirmatory lung cancer liquid biopsy tests, depending on market penetration and reimbursable pricing.

"Having our CLIA laboratory become operational marks the beginning of our commercial activities in the U.S., a key driver of our long-term success. The receipt of CLIA certification is a testament to the dedication and proficiency of our operations team in Alameda and I am grateful for the team members' tireless efforts in achieving this important milestone," said Bill Annett, President and CEO. "The demand for molecular diagnostic testing for cancer is growing rapidly and CLIA certification of our laboratory positions OncoCyte to enter this exciting emerging field."

Mr. Annett continued, "We believe DetermaVu™ will aid physicians in the early diagnosis of lung cancer and in a majority of cases eliminate the need for expensive, invasive lung biopsies. We expect that a reduction in the number of lung biopsies performed annually, coupled with improvements in treatment at an early stage of disease, could lead to a significant reduction in the cost burden to the healthcare system while improving the survival rate of lung cancer patients."

About CLIA

Under CLIA, a laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. CLIA requires that the Company holds a certificate applicable to the complexity of the categories of testing performed and that compliance with certain standards. CLIA further regulates virtually all clinical laboratories by requiring that they comply with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that the clinical laboratory testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to be reimbursed for services provided to state and federal health care program beneficiaries.

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.

DetermaVu™ is a trademark of OncoCyte Corporation.

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 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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