



OncoCyte Submits Application for CLIA Certification of its Laboratory

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Achieving Certification is Key Step for Planned Commercial Launch in the Second Half of 2017

ALAMEDA, Calif., March 21, 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, has submitted its application for CLIA certification of its laboratory, the next step towards its objective of launching the Company's first commercial product, a lung cancer diagnostic test, in the second half of 2017. The Company expects to receive the certification during the second quarter of 2017.

"This is an exciting next step for OncoCyte as CLIA certification is a key component of our plan to commercially launch our lung cancer diagnostic test during the second half of this year," commented William Annett, President and Chief Executive Officer. "Upon receipt of CLIA certification we 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. Once this lab validation study is completed, we will initiate a clinical validation study of 300 blinded, prospectively collected samples. If the results replicate the positive results of our prior study, we will move to commercialization. Based on our estimate of the number of patients who could be candidates for our lung cancer diagnostic, we believe the total addressable market for the test could be over \$4 billion, depending on efficacy and reimbursable pricing. Additionally, use of the test will reduce healthcare costs for unnecessary biopsy procedures and complications."

On March 6, 2017, OncoCyte reported the successful results of its lung cancer diagnostic test and the Company's algorithm confirmed the results of an earlier study by The Wistar Institute of Anatomy and Biology. The Area Under the Curve (AUC) in Wistar's study was 0.82 with a sensitivity of 90% and specificity of 62%, exceeding levels OncoCyte believes are necessary for a commercially successful test. 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. The complete data results of OncoCyte's R&D study will be presented at The American Thoracic Society (ATS) 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.

OncoCyte's clinical laboratory is headed by William K. Seltzer, a Board Certified Clinical Medical Geneticist. He joined OncoCyte in September 2014 and in July of 2015 was appointed Vice President of Clinical Services. Dr. Seltzer has 30 years of commercial and academic experience in clinical diagnostic services and product development and commercialization, quality assurance and regulatory compliance. Over the course of his career, Dr. Seltzer has been responsible for the successful launch and oversight of clinical

services for over 100 Laboratory Developed Tests (LDTs). He has published more than 50 articles in peer-reviewed scientific journals and is co-inventor on patents for molecular diagnostics and methods.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 254,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program.

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 diagnostic test studies, commercialization plans, future financial and/or operating results, future growth in research, technology, clinical development, and potential market opportunities for OncoCyte’s diagnostic tests, 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, diagnostic test pricing, 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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