

# ONCOCYTE ANNOUNCES SUCCESSFUL COMPLETION OF CLIA LAB VALIDATION STUDY OF ITS DETERMAVU™ LUNG CANCER DIAGNOSTIC TEST; CLINICAL VALIDATION STUDY INITIATED

Sep 27, 2017

### **DetermaVu™ Launch Planned for Fourth Quarter 2017**

ALAMEDA, Calif., Sept. 27, 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 that its CLIA laboratory has successfully completed a rigorous validation study of DetermaVu™, OncoCyte's diagnostic test for lung cancer. In this study, OncoCyte assayed approximately 120 samples previously tested in its 299-patient study presented at the American Thoracic Society conference in May 2017, with the goal of demonstrating that OncoCyte's new clinical laboratory provides the same results on clinical samples as those obtained in its R&D lab. The results met all performance criteria, demonstrating the accuracy and robustness of the assay as performed in the Company's CLIA laboratory. The CLIA lab validation study included specific protocols to confirm the accuracy, reproducibility, and precision/repeatability of DetermaVu™.

"The laboratory staff and procedures in place in the clinical laboratory have been confirmed to provide accurate, reliable, consistent and reproducible results," said William Seltzer, PhD, FACMG, VP of Clinical Services and the Laboratory Director for OncoCyte. "The results were consistent with the positive data reported at the American Thoracic Society 2017 International Conference, and have enabled us to initiate our Clinical Validation Study, the final step prior to the commercial launch of DetermaVu™."

The Clinical Validation Study has now begun and is expected to be completed in the fourth quarter of 2017. In this study, approximately 300 new blinded blood samples, which have been prospectively collected will be assayed in the CLIA lab using DetermaVu™. The performance of the test will be assessed against the clinical diagnosis of the patients from whom the samples were collected. If the Clinical Validation Study is successful and the results meet commercial requirements, OncoCyte will commence the commercial launch of DetermaVu™.

"Successful completion of the CLIA Lab Validation Study is another important step toward launching DetermaVu™," said William Annett, President and Chief Executive Officer. "We plan to complete the ongoing Clinical Validation Study in the fourth quarter."

OncoCyte believes that widespread utilization of DetermaVu<sup>™</sup> could result in a substantial reduction in the number of unnecessary, expensive lung biopsies performed annually in the U.S., with a corresponding reduction in the surgical risk to patients undergoing biopsy procedures. Broad use of DetermaVu<sup>™</sup> would result in a fundamental advancement in the diagnosis of suspicious lung nodules by allowing physicians to determine more accurately which patients need biopsies and which patients only need follow-up imaging. The Company estimates that approximately 1.4 million patients annually in the

U.S. could benefit from the DetermaVu<sup>™</sup> test. Depending on market penetration and reimbursable pricing, this could translate into a market opportunity of up to \$4.7 billion annually.

## **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 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 forwardlooking statements, except as required by law.

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