# ONCOCYTE COMPLETES SUCCESSFUL TRANSITION TO NEW DIAGNOSTIC TESTING PLATFORM AND INITIATES DETERMAVU™ DEVELOPMENT STUDIES

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*Initiates Algorithm Development Study to Establish Accuracy in Interpreting Assay Results*

*On-Track for Pivotal R&D Validation Study Results by Approximately Year End, with Commercial Availability Planned for 2H 2019*

ALAMEDA, Calif., Oct. 29, 2018 (GLOBE NEWSWIRE) -- **OncoCyte Corporation (NYSE American: OCX)**, a developer of novel, non-invasive tests for the early detection of cancer, today provided an update on its successful transition to a new diagnostic testing platform and initiation of a series of studies designed to make its DetermaVu™ lung cancer assay available for the medical market in the second half of 2019.

OncoCyte has completed its transition to an industry standard Next Generation Sequencing (NGS) diagnostic testing platform, including installation, training and operational qualification. The Company has also completed incoming quality control and testing of its custom panel reagents. As anticipated, the new platform appears to be generating consistent and reliable data.

Based on these positive results, OncoCyte has initiated the 700-blood sample Algorithm Development Study to establish a proprietary mathematical algorithm that will be used to interpret test results for DetermaVu™.

“We are pleased to complete the transition to our new diagnostic testing platform, an important step forward as we continue to advance DetermaVu™ toward commercialization,” said William Annett, President and Chief Executive Officer. “With the platform in place and generating reliable test results, we look forward to completing our critical R&D Validation Study around year-end. Assuming we are successful with that study, we will be on-track to complete all of the necessary pre-launch studies in the first half of 2019. We believe DetermaVu™ can alter the treatment paradigm in lung cancer diagnostics by reducing the number of expensive, risky and unnecessary biopsies, thereby saving lives while lowering healthcare costs. If high accuracy is confirmed in the planned studies, DetermaVu™ could address an estimated $4.7 billion annual market in the U.S. for confirmatory lung cancer liquid biopsy tests, depending on pricing, market penetration, and the attainment of Medicare and private payer reimbursement.”

Management will provide an update on DetermaVu™ development during its next regularly-scheduled quarterly results conference call in mid-November.

**DetermaVu™ Development Path**

To provide an initial assessment of the accuracy of DetermaVu™, OncoCyte will analyze and cross-validate a proprietary DetermaVu™ algorithm in multiple clinical subsets using 700 blood samples gathered from patients. OncoCyte has discovered or in-licensed almost 800 biomarkers that may, in combination, differentiate between malignant and benign lung nodules. The optimal combination and weighting of biomarkers in the algorithm will be determined through bioinformatics combined with the latest algorithm development strategies that may include artificial intelligence (AI) related methods.

This study follows an earlier 2018 study of DetermaVu™ on approximately 155 clinical samples that resulted in accuracy (as measured by Area Under the Curve data) at least equivalent to the DetermaVu™ lung cancer test results previously reported in May 2017 at the American Thoracic Society 2017 International Conference (ATS). Those results demonstrated sensitivity of 95%, specificity of 73%, and Area Under the Curve (AUC) of 0.92, meaning that 92% of samples were correctly identified. 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. Because the error bar or potential range of results from the small sample set in the 2018 study is wide, these results must now be confirmed in a larger sample set.

Upon completing the Algorithm Development Study, OncoCyte plans to initiate an R&D Validation Study to confirm the accuracy of DetermaVu™ in a research setting. This R&D Validation Study will analyze approximately 250 blinded, prospectively collected patient blood samples to confirm the sensitivity and specificity of DetermaVu™ to within approximately plus or minus 8 percentage points. Expected about year end, results of the R&D Validation Study should provide a strong indication of whether DetermaVu™ has sufficient accuracy for medical use.

If OncoCyte achieves positive R&D Validation study results, the next step will be to conduct an Analytical Validation Study to establish the performance characteristics of DetermaVu™, which will then be validated in the Company's CLIA laboratory. Finally, as the last step in the DetermaVu™ development process, a blinded prospective Clinical Validation Study of DetermaVu™ would be conducted in the first half of 2019.

All clinical samples required for each of these DetermaVu™ studies are currently in-house, and available for testing. In total OncoCyte has blood samples from over 2,000 patients.

**About DetermaVu™**

DetermaVu™ is OncoCyte's confirmatory, non-invasive, liquid biopsy test intended to facilitate clinical decision making in lung cancer diagnosis. DetermaVu™ is being developed as an intermediate step to confirm the absence of cancer between imaging modalities (LDCTs) detecting suspicious lung nodules and downstream invasive procedures to determine if the nodules are malignant. OncoCyte estimates that a $4.7 billion annual market could develop in the U.S. for its confirmatory lung cancer liquid biopsy test, depending on market penetration and reimbursable pricing.

DetermaVu™ is a trademark of OncoCyte Corporation.

**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. Early detection of cancer can improve health outcomes, reduce the cost of care, and improve patients' quality of life. Liquid biopsy diagnostic tests like those OncoCyte is developing may reduce the need for costlier and riskier diagnostic procedures such as invasive biopsy procedures. OncoCyte's is focusing its efforts on developing DetermaVu™ as a non-invasive confirmatory diagnostic test for lung cancer. DetermaVu™ is being

developed using proprietary sets of genetic and protein molecular markers to detect the presence of lung cancer. OncoCyte also plans to conduct research to identify additional molecular markers, acquire or license markers and related technology, and develop cancer tests based on those markers.

**OncoCyte 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 capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, 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.

**Investor Contacts**

Bob Yedid
LifeSci Advisors, LLC
bob@lifesciadvisors.com
646-597-6989

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