# OncoCyte Announces Successful Results of DetermaVu™ R&D Validation Study

Jan 29, 2019

*Results show 90% sensitivity and 75% specificity, demonstrating best-in-class performance*

*On track for commercial availability of DetermaVu™ Lung in 2H 2019*

*Results suggest the potential to address a U.S. market opportunity of $4.7 billion*

*Unique immune system interrogation approach may have potential for early detection of other cancers*

*Company to host conference call today at 8:30am ET*

ALAMEDA, Calif., Jan. 29, 2019 (GLOBE NEWSWIRE) -- **OncoCyte Corporation (NYSE American: OCX)**, a developer of novel, non-invasive tests for the early detection of cancer, today announced positive results from its key R&D Validation study demonstrating the accuracy of the Company's DetermaVu™ liquid biopsy test for lung cancer.

The R&D Validation study demonstrated a sensitivity of 90% (95% CI 82%-95%) and specificity of 75% (95% CI 68%-81%) of DetermaVu™ on a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators. Sensitivity is the percentage of malignant nodules that are correctly identified and specificity is the percentage of benign nodules correctly identified. A 95% confidence interval (CI) suggests that there is a 95% chance that final test performance will be within the stated range.

These results show that DetermaVu™ significantly exceeds the critical parameters necessary for use in lung cancer diagnosis and that DetermaVu™ clearly outperforms reported results from competitors' tests and other clinical models. Based on this strong performance, OncoCyte believes that DetermaVu™ is the best-in-class lung cancer liquid biopsy diagnostic test. OncoCyte plans to make DetermaVu™ commercially available in the second half of 2019, with the goal of fundamentally changing the way lung cancer is diagnosed.

Notably, OncoCyte obtained these results without including any clinical factors in the DetermaVu™ algorithm, underscoring the strength of the test. DetermaVu™ measures biomarkers of the immune system's response to cancer to differentiate between malignant and benign lung nodules in early stage lung cancer. Because clinical data points, such as lung nodule size, provide a significant amount of the diagnostic power for liquid biopsy lung cancer tests developed by other companies, the superior accuracy of DetermaVu™ independent of any clinical factors reinforces its strength as a differential diagnostic tool for early lung cancer detection, and provides physicians with significant biologic information that has not been available prior to DetermaVu™.

DetermaVu™ has the potential to dramatically reduce U.S. healthcare costs by billions of dollars each year by eliminating unnecessary biopsies, which, according to a recent Medicare study, cost on average $14,634 each. In addition, DetermaVu™ can provide great benefit to patients by avoiding invasive biopsies and the complications that arise in up to 24% of those procedures, and deaths that occur in up to 1% of cases.

In practice, physicians could use a simple DetermaVu™ blood test to determine whether or not a patient's lung nodule should be biopsied for cancer. If the DetermaVu™ test indicates a benign result, the patient can be monitored without a biopsy, eliminating the cost and safety risks of an invasive procedure. With 75% specificity, physicians could use DetermaVu™ to eliminate up to three quarters of unnecessary biopsies and their associated complications and deaths. These reduced costs and improved patient outcomes highlight DetermaVu™'s value proposition for payers such as Medicare and health insurance companies.

The R&D Validation study utilized the optimized biomarkers and algorithm that were previously identified in the Company's recently completed Algorithm Development study, based on 700 patient samples.

**R&D Validation Study Highlights:**

- DetermaVu™ demonstrated sensitivity of 90% (95% CI 82%-95%), and specificity of 75% (95% CI 68%-81%) in a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators, and without the use of clinical factors such as nodule size
- Results are the first ever in a blinded prospective study to confirm OncoCyte's approach of utilizing the immune system's response to early stage cancer to provide a robust biological signal in blood that supports physicians in differentiating between malignant and benign lung nodules
- These results are consistent with previous studies of DetermaVu™, even though this study achieved statistically equivalent results using biomarkers alone, without the use of clinical factors such as nodule size, further confirming the strength and robustness of the biomarkers in the assay
- The Company's immune system interrogation approach overcomes significant challenges and limitations associated with early stage lung cancer detection using other liquid biopsy approaches, such as circulating tumor cell and cell free DNA detection, which have failed to demonstrate sensitivity and specificity characteristics comparable to DetermaVu™, particularly in early stage lung cancer patients

Lyndal Hesterberg, Ph.D., Senior Vice President of Research and Development of OncoCyte, stated, "These results serve to validate OncoCyte's immune system interrogation approach and are a significant scientific advancement in the field of liquid biopsy with three main achievements: First, we have demonstrated that the biological basis for DetermaVu™, that is, gene expression changes within the immune system in response to cancer, can serve as a highly sensitive and accurate signal in blood for early stage lung cancer diagnosis. Second, we have shown for the first time in a prospective cohort of blinded samples, and without the use of any clinical factors, that DetermaVu™ has the sensitivity and specificity required for clinical use."

Dr. Hesterberg, added, "Finally, we believe that our approach, using a liquid biopsy to leverage the exquisite sensitivity of the body's immune response to cancer, might have broad application in detecting other early stage malignancies. We are planning to investigate the use of this unique immune system interrogation approach in other cancer types."

William Annett, President and Chief Executive Officer of OncoCyte, said, "We believe DetermaVu™ is poised to establish a new paradigm for diagnosing individuals at risk of lung cancer while addressing a multibillion-dollar market opportunity. Physicians need better tools to diagnose malignant versus benign

lung nodules in order to reduce the large number of unnecessary lung biopsies that create risks for patients and are costly to the healthcare system. The successful completion of our prospective cohort, blinded R&D Validation study confirms that DetermaVu™ significantly exceeds the key criteria essential for a viable commercial product. We are thrilled by these findings and are proceeding quickly with our commercial planning, with the goal of making DetermaVu™ commercially available in the second half of 2019."

**Remaining DetermaVu™ Development Steps**
Having achieved successful R&D Validation utilizing the robust and reproducible Thermo Fisher Ion GeneStudio S5 next-generation sequencing platform, OncoCyte is working to complete the remaining steps to make DetermaVu™ commercially available in the second half of this year: Analytical Validation, CLIA Validation and Clinical Validation.

These steps may be completed in rapid succession because the Company has all the necessary patient samples in-house. The Analytical Validation study is designed to establish performance characteristics of the assay system, which will then be validated in the Company's CLIA-certified laboratory in Alameda California. As the final laboratory step prior to DetermaVu™ commercialization, OncoCyte will initiate a Clinical Validation study in its CLIA lab, which will analyze approximately 350 blinded, prospectively-collected patient samples for final confirmation of test sensitivity and specificity.

**Conference Call and Webcast Details:**
OncoCyte's management team will conduct a live conference call and webcast today at 8:30 a.m. Eastern

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| Webcast: | The live webcast can be accessed at www.oncocyte.com |
| Telephone: | U.S. dial-in: 877-407-9716 |
| International dial-in: | 201-493-6779 |
| Access code: | 13686862 |

The webcast replay will be available on the company's website approximately 2 hours following completion of the call.

**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 a confirmatory test for presence or absence of lung cancer to reduce the need for unnecessary invasive biopsies when suspicious lung nodules are detected by imaging modalities such as x-rays or other scans. OncoCyte estimates that an annual market of up to $4.7 billion 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 ("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 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.

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