OncoCyte Announces Initiation of Analytical Validation Study

Mar 04, 2019

Company remains on-track for commercial availability of DetermaVu™ Lung in 2H 2019

ALAMEDA, Calif., March 04, 2019 (GLOBE NEWSWIRE) -- **OncoCyte Corporation (NYSE American: OCX)**, a developer of novel, non-invasive tests for the early detection of cancer, today announced the initiation of the Company's Analytical Validation study of DetermaVu™ Lung, its liquid biopsy test for lung cancer.

Having recently achieved very positive results from its R&D Validation study, OncoCyte is now working to complete the remaining development studies required for commercialization of DetermaVu™, including Analytical Validation, CLIA Validation and Clinical Validation. Assuming positive results from these studies, the Company remains on-track to make its DetermaVu™ lung cancer assay commercially available in the second half of 2019.

William Annett, President and Chief Executive Officer of OncoCyte, stated, "We are very pleased to have initiated the Analytical Validation study, the next critical step toward the completion of development of DetermaVu™. Importantly, we already have in-house all of the required patient blood samples, allowing us to advance efficiently through this study. We anticipate making DetermaVu™ commercially available later this year and believe our immune system interrogation approach has the potential to fundamentally change the way lung cancer is diagnosed."

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. The studies required for Analytical Validation are established in the Clinical Laboratory Standards Institute (CLSI) Guidelines. These guidelines cover the testing for such matters as limits of quantitation, precision, reproducibility, and interfering substances. Successful completion of the study will establish the performance characteristics of DetermaVu™ and if the upcoming CLIA Validation and Clinical Validation studies are successful, will allow for use under real world conditions.

Results of R&D Validation study of DetermaVu™

OncoCyte's recently-completed R&D Validation study of DetermaVu™ demonstrated sensitivity of 90% (95% CI 82%-95%) and specificity of 75% (95% CI 68%-81%) on a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators. These results were achieved without including any clinical factors in the DetermaVu™ algorithm, and significantly exceed the critical parameters the Company believes are necessary for use in lung cancer diagnosis. 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.

About DetermaVu™

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 that 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™ 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.

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'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 tests for additional types of cancer 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

Media Contact

Allison Blum, Ph.D.
LifeSci Public Relations
allison@lifescipublicrelations.com
646-627-8383

Source: OncoCyte Corporation

Powered by SITECORE