OncoCyte Reports Encouraging New Study Results for Lung Cancer Blood Test

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- Results suggest improved performance of next-generation test
- Study results support move to new diagnostic testing platform
- Significant development work required to fully validate this recent progress

ALAMEDA, Calif., July 09, 2018 (GLOBE NEWSWIRE) -- **OncoCyte Corporation** (NYSE American:OCX), a developer of novel tests for early detection of cancer, today reported that its most recent study of clinical samples in the development of DetermaVu™, its lung cancer diagnostic blood test, has produced encouraging results. This study supports moving the test to a leading clinical diagnostic testing platform and indicates that the clinical performance of the test may be better than was previously expected.

The move to a leading diagnostic testing platform is expected to resolve the inconsistent data issues OncoCyte encountered with the diagnostic testing platform it had previously used in the development of DetermaVu™. OncoCyte believes that the precision of Next Generation Sequencing (NGS) platforms may increase test performance. In addition, the use of a NGS platform could allow for decentralized operations beyond OncoCyte's CLIA lab, potentially enabling development of a CE marked kit product for distribution in Europe and other markets, if OncoCyte's upcoming studies are successful.

In addition, the study incorporated newly discovered biomarkers into a new, next-generation version of DetermaVu™. These biomarkers appear to be more robust than those used in the earlier biomarker panel and may enhance the utility and accuracy of DetermaVu™. The use of the new biomarkers in combination with the existing Wistar biomarkers achieved encouraging results even without the inclusion of clinical data such as nodule size, while the original DetermaVu™ algorithm included nodule size as a contributing factor.

The study found that an enhanced algorithm incorporating the best-performing new biomarkers with the best-performing biomarkers used in previous DetermaVu™ studies yielded accuracy results (as measured by Area Under the Curve (AUC) data) equivalent or superior to results of previous studies using the earlier biomarker panel and algorithm. Because the error bar or potential range of results from the small sample set in the study is wide, these results must be confirmed in a larger sample set.

This most recent study was performed on two assay platforms, the Illumina Nova Seq 6000 and Thermo Fisher Chef-S5. DetermaVu™ ran successfully on both platforms. OncoCyte anticipates that the use of one of these widely commercialized diagnostic platforms will increase the likelihood that DetermaVu will offer the consistent and robust results necessary for product development and commercial operations.

"We are extremely pleased with the results of this study, which provide us with a new diagnostic testing platform and a route forward for the development of a next-generation DetermaVu™," said William

Annett, President and Chief Executive Officer.

Lyndal Hesterberg, Senior Vice President of Research and Development, stated, “The study results are very encouraging. Although further studies testing larger numbers of samples are necessary, it appears the addition of the new biomarkers in DetermaVu™ may enhance the accuracy of our diagnostic test.”

While these initial results are very encouraging, significant development work remains. OncoCyte will engage in a series of studies intended to retrain and validate the algorithm on the new platform. The company will further test its biomarkers on a broader set of clinical samples, with the goal of selecting the optimal biomarker panel and algorithm.

OncoCyte is currently in the process of moving to the new platform. Next, OncoCyte will perform a prospective, blinded R&D Validation Study on approximately 250 patients to assess the performance of the algorithm in a blinded set of clinical samples. If successful, the R&D Validation Study will be followed by an Analytical Validation Study in the Company’s CLIA laboratory. Finally, OncoCyte plans to conduct a Clinical Validation Study to confirm test performance. OncoCyte has collected all the samples it expects to require for the R&D Validation study.

With the necessary samples in hand, OncoCyte has expanded the R&D Validation study protocol to include a larger number of samples than were used in the comparable 2017 study. This larger sample set is intended to provide OncoCyte with a clearer picture of the potential accuracy of DetermaVu™, and more confidence in the results expected in the Clinical Validation Study that will follow. OncoCyte’s goal is to complete the expanded R&D Validation Study by the end of 2018 and to complete the Clinical Validation Study during the first half of 2019.

OncoCyte believes that it has the opportunity to create a highly accurate test which, if confirmed in a large clinical data set, could successfully address what it estimates could be a $4.7 billion annual market in the U.S. for confirmatory lung cancer liquid biopsy tests, depending on pricing, market penetration, and the availability of Medicare and private payer reimbursements.

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 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™ 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 and cystoscopic procedures. OncoCyte’s development pipeline is focused on non-invasive confirmatory diagnostic tests for lung, breast, and bladder cancer. OncoCyte’s tests are being developed using proprietary sets of genetic and protein molecular markers that differentially express in specific types of cancer. OncoCyte conducts ongoing research to identify

additional molecular markers, acquire or license markers and related technology, and develop 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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