OncoCyte Announces Initial Results of DetermaVu™ Feasibility on New Platforms; Enhancements May Increase Lung Cancer Diagnostic Test's Clinical Performance

Mar 08, 2018

Company Anticipates Commercial Launch During 2018

ALAMEDA, Calif., March 08, 2018 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE American:OCX), a developer of novel, non-invasive liquid biopsy tests for the early detection of cancer, today provided an update on the development and commercial launch timeline of DetermaVu™, its liquid biopsy lung cancer diagnostic test.

As reported in November 2017, during the process of running initial samples for the Clinical Validation Study inconsistent analytic results were observed by OncoCyte's technical team. OncoCyte determined that this was caused by a variance in the lots of consumables used in the sample-processing system that analyzes blood samples for markers that may indicate whether lung nodules found in patients are benign or suspicious. OncoCyte has been actively engaged with NanoString to more completely understand the issues that have delayed the DetermaVu™ validation study. The work with NanoString is ongoing. The work to date continues to support OncoCyte's conclusion that the previous studies of DetermaVu™ were not impacted by this consumables issue and the positive results reported previously have not changed.

In addition to assessing the NanoString platform's commercial applicability, OncoCyte is actively evaluating alternative assay platforms for use with its molecular biology diagnostic testing. OncoCyte is announcing the encouraging initial results of its initial clinical sample feasibility study on the Illumina Sequencing platform. The Illumina platform is a market-leading platform for molecular biology testing in the clinical Laboratory Developed Test (LDT) space. While further testing is needed, OncoCyte's initial results indicate that the Illumina platform could provide consistent and robust support for the further clinical development studies that are necessary for the commercialization of DetermaVu™.

Lyndal Hesterberg, OncoCyte's Senior Vice President of Research and Development, stated, "The initial feasibility results on an established clinical platform may provide OncoCyte with an alternative path to clinical validation and commercial launch of the DetermaVu™ product in 2018. We will be pursuing the next steps to further assess the Illumina platform, along with other commercially established clinical molecular testing platforms, and we are encouraged by the results of this initial feasibility study."

OncoCyte has also identified ways that potentially may enhance the lung cancer signal identified by DetermaVu™ and has incorporated this approach into a revised algorithm. This revised algorithm was tested on about 60 clinical samples and resulted in accuracy (as measured by Area Under the Curve (AUC)

data) equivalent or superior to previously reported results, although the error bar or potential range of results from this small sample set is wide and the results must be confirmed in a larger sample set.

Because of these developments, OncoCyte is extending its evaluation of the commercial molecular diagnostic platforms by doing a follow-on study utilizing a larger set of clinical samples. The Company expects to complete the process during the second quarter of 2018. After concluding this process, data will be available to determine which platform delivers the most accurate, consistent and robust test results while maintaining a reasonable cost of goods. The Company then intends to complete product development on the selected platform by carrying out an R&D Validation Study followed by an Analytical Validation Study. If these studies are successfully completed, OncoCyte intends to conduct a Clinical Validation Study. Clinical validation is the final step prior to commercial launch, which is still anticipated during 2018. OncoCyte has collected all the samples necessary for carrying out all these studies.

“The results from our recent evaluation of commercially available molecular testing platforms support our continued confidence in DetermaVu™ as a confirmatory test for the diagnosis of early stage lung cancer,” commented William Annett, President and Chief Executive Officer.

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.

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 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.

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:

EVC Group LLC
Matt Haines / Michael Polyviou
917-733-9297 / 732-933-2754
mhaines@evcgroup.com /mpolyviou@evcgroup.com

Financial Media Contact:

GIBSON Communications, LLC
Tom Gibson
201-476-0322
tom@tomgibsoncommunications.com