OncoCyte Provides Updated Timelines on Diagnostic Test Development and Commercialization Plans

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Breast Cancer Test Development Three to Six Months Ahead of Schedule; Commercial Launch Possible in Mid to Late 2018

Lung Cancer Test Development Two to Three Months Behind Schedule; Commercial Launch Planned for Second Half of 2017

ALAMEDA, Calif., Jan. 04, 2017 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE MKT:OCX), a developer of novel, non-invasive blood and urine based tests for the early detection of cancer, today provided an update on the development of its product portfolio that currently includes a lung cancer diagnostic test, a breast cancer diagnostic test and a bladder cancer diagnostic test. 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.

“We enter 2017 with a focus on late stage development as we prepare to commercialize our diagnostic tests, which address much larger opportunities than most other diagnostic tests. We have heard consistently from physicians and health insurers that our tests are very much needed to help avoid costly, invasive and unnecessary procedures,” said William Annett, President and CEO of OncoCyte. “Our breast cancer test development is now progressing ahead of schedule and we anticipate achieving additional development milestones for this program in the year ahead. Our work in developing the lung cancer diagnostic test is proceeding across the clinical study, product development, CLIA lab, and commercial areas. The clinical study timeline has been delayed by slower than expected sample collection; while we have received all of the benign samples that we need for our study we require an additional 7 to 14 malignant samples. We expect to complete the next steps of the lung test development process during the first quarter of the year. We continue to be excited about the positive data that was reported for our bladder cancer test at ASCO in June 2016, but are likely to seek a commercialization partner because (unlike our lung and breast cancer tests) the marketing challenges of the bladder cancer test would likely require the resources of a larger company. OncoCyte is committed to developing high value tests that address large market opportunities while keeping our cash burn rate low prior to commercialization.”

Breast Cancer Diagnostic Test Development Ahead of Schedule

OncoCyte today reported the commencement of a biomarker training and optimization study as the next phase of development of its internally developed breast cancer diagnostic test. This study will use blood samples from 300 benign and malignant breast cancer patients, all of which have now been collected.

The purpose of the optimization and training study is to attempt to replicate the successful findings that were presented by OncoCyte at the San Antonio Breast Cancer Symposium (SABCS) in December. OncoCyte reported on its initial 100 sample study of a novel panel of serum protein biomarkers designed to allow for the non-invasive and sensitive detection of breast cancer in BI-RADS category 4 patients. The 15-marker model resulted in an area under the curve (AUC) of 0.92 sensitivity of 90% and specificity of 76%. The AUC of a test is a measure that combines sensitivity and specificity to express its total accuracy, with 1.0 being perfect accuracy and 0.50 being a random result. 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. OncoCyte expects to complete this 300-patient study during mid-2017, which would put development of the diagnostic test substantially ahead of the previously announced schedule.

"The results we reported at SABCS were well received by clinicians and researchers and have led our team to dedicate more resources to our breast cancer diagnostic test development program," said Mr. Annett. "If our efforts are successful, our test will address one of the more pressing needs in oncology today…the need to reduce over-treatment of women with suspicious breast imaging findings. Our next phase of development for this test is to attempt to replicate the findings presented at SABCS in a larger, approximately 300-patient study. At this point, we are ahead of our internal development plan for this test by three to six months and believe we may be able to commercially launch it in mid to late 2018."

Each year approximately 38 million women in the United States undergo mammogram screenings. Mammograms detect suspicious lumps or masses in about 1.5 to 2 million of these women, known as BI-RADS category 4 patients, who then are referred for an invasive follow-on breast biopsy to determine if the mass is malignant or benign. However, only about 20% of these biopsies result in a cancer diagnosis. Consequently, the majority of breast biopsies are not needed and can result in unnecessary pain, discomfort and anxiety to women as well as an estimated $2.8 billion annual cost to the healthcare system. OncoCyte's test is designed to be used as an adjunct to suspicious mammography results to help reduce the number of avoidable biopsies.

If the training and optimization study results confirm the findings presented at SABCS, an algorithm validation study of up to 500 patients, followed by a separate clinical validation study in OncoCyte's CLIA lab, would need to be successfully completed prior to commercial launch.

Lung Cancer Diagnostic Test Development

OncoCyte continues to conduct a 300-patient study of its lung cancer test and now expects to complete the analysis by the end of the first quarter of 2017, which is up to a quarter later than its original target date. The delay is primarily due to the slowing of sample collection during the holiday period and the uncontrollable randomization rate of collecting malignant tumor versus benign samples. OncoCyte has collected all of the necessary benign samples and presently expects that by the end of January it will receive the additional 7 to 14 malignant samples needed to complete the study.

OncoCyte's study is utilizing approximately 300 samples being collected from 38 oncology centers in the United States to finalize the product's prediction algorithm and to test its accuracy. All of the samples will be focused specifically on patients with nodule sizes from 5 to 30 millimeters, the intended use population for the test.

In December, OncoCyte completed a market research study of 180 physicians which, combined with a health economic outcomes study, leads the Company to believe that a successful confirmatory lung cancer test must have a sensitivity of at least 85% and a specificity of at least 30%. OncoCyte's ongoing 300-patient study is a follow-on study to the Wistar Institute study, which reported a test sensitivity of 90% and specificity of 62% at the CHEST 2016 Annual Meeting. If OncoCyte's 300-patient study achieves

either the range specified by physicians or duplicates previous studies, OncoCyte may have the first commercial blood test that can help physicians to better manage patients presenting with lung nodules to determine which ones should be biopsied and which ones should continue with regular non-invasive monitoring, thereby helping to avoid unnecessary lung biopsies.

As well as continuing the 300 patient study, OncoCyte is also progressing with work in the three other areas involved in bringing a diagnostic test to market – product or operational development, the CLIA lab where patient samples are analyzed, and commercialization. For example, in the product development area OncoCyte is focused on finalizing the test's specific algorithms used to determine sensitivity and specificity as well as working closely with its suppliers to optimize reagent and system parameters and metrics to ensure consistent, reliable results from the third party equipment and reagents being used to analyze samples.

As these operational processes are being established and verified, the Company must complete several steps to obtain CLIA certification. OncoCyte's CLIA lab is now operational, the lab equipment has been qualified for clinical use, and the lab is fully staffed with a board certified Clinical Laboratory Director, a clinical supervisor and a licensed technologist. This team is currently being trained in OncoCyte's lung product testing methodology, and a Director of Quality Assurance has recently been hired. OncoCyte expects to apply for CLIA certification of the lab following the completion of its current lung cancer study. Upon CLIA certification OncoCyte will carry out a CLIA validation study using the finalized processing algorithm and operational procedures on a new set of at least 300 blinded samples.

On the commercialization planning front, OncoCyte has ramped up several of the marketing and market access functions required for a launch of the lung cancer diagnostic test and expects to be making key medical affairs and sales hires if the outcome of the current lung cancer study is favorable. OncoCyte has also begun planning the implementation of the commercial systems and infrastructure necessary for launch, including customer relationship management, billing, fulfillment, and reporting processes and systems.

If the steps described above are successful, a commercial launch of the test could occur in the second half of 2017.

Bladder Cancer Diagnostic Test Development

In June 2016 at ASCO (the American Society of Clinical Oncologists), OncoCyte presented the results of a 241 patient study that demonstrated the feasibility of OncoCyte's non-invasive, urine-based test to detect bladder cancer and to distinguish between high-grade and low-grade cancers. The test for the detection of high-grade urothelial carcinoma in patients presenting with hematuria performed with an AUC of 0.93, while for low-grade performed with an AUC of 0.81. Commercializing a bladder cancer diagnostic test would require a much larger salesforce than would be required to commercialize either the lung or breast cancer tests. Therefore OncoCyte continues to examine strategies, including partnering the product, to fund late stage development and commercialization of the bladder cancer test.

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, bladder and breast 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) should also be considered to be forward-looking statements. These statements include those pertaining to the implementation and results of our validation study and other studies, commercialization plans, future financial and/or operating results, future growth in research, technology, clinical development, and potential 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 and other patient sample studies or regulatory approvals, reliability of third party reagents and equipment, the need and ability to obtain future capital, and maintenance of intellectual property rights, and the need to obtain third party reimbursement for patient’s use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and as such 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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