OncoCyte Presents Positive Data from its Liquid Biopsy Breast Cancer Diagnostic Test at the San Antonio Breast Cancer Symposium

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Study Results in Encouraging AUC Score of .935

ALAMEDA, Calif., Dec. 07, 2017 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE American:OCX), a developer of novel, non-invasive liquid biopsy tests for the early detection of cancer, today presented positive data from its most recent breast cancer diagnostic test study at the 2017 San Antonio Breast Cancer Symposium (SABCS). The data were presented by Philip McQuary, Ph.D., Director of Product Development at OncoCyte.

This study revealed that a novel blood based diagnostic test may allow for the non-invasive and sensitive detection of breast cancer in BI-RADS category 4 patients, thereby differentiating women who have breast cancer from those who do not. A 19-marker model resulted in an AUC of 0.935 with a sensitivity of 90% and specificity of 82%. The data from this study are consistent with data reported at the San Antonio Breast Cancer Symposium in December 2016.

The poster, titled “Assessment of an Immune Response Panel of Serum Protein Biomarkers for the Non-Invasive Detection of Breast Cancer,” discusses details of OncoCyte’s study in which serum samples were collected at four U.S. sites from 136 women with suspicious diagnostic mammography findings undergoing biopsy to determine if they have breast cancer. All 136 subjects had mammograms and were classified as BI-RADS category 4 and had pathology confirmation of their diagnosis (malignant or benign). Statistical screening methodologies were used to identify markers with the potential to distinguish benign from malignant pathology. The candidate markers were further studied and combined to develop a potential diagnostic test.

BI-RADS (Breast Imaging and Reporting Data System) is a scoring system developed by the American College of Radiologists to help clinicians assess the risk of cancer in women with a lump or mass. A BI-RADS category 4 classification indicates a suspicious result, and women in this category are generally referred for a breast biopsy. 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 lumps or lesions that are identified correctly by the test and specificity measuring the percentage of benign lumps or masses correctly identified.

The current standard of care for breast cancer diagnosis – annual or biannual mammogram screenings – does not meet the needs of large populations of women for whom mammography alone is not sufficient. These populations include women with dense breast tissue, genetic mutations (BRCA), a family history of breast cancer, or those who have suspicious mammogram screening results (BIRADs 3 or 4). The Company’s non-invasive liquid biopsy breast cancer diagnostic is intended to be a confirmatory, post-

mammogram test that potentially would reduce the number of patients subjected to invasive breast biopsy procedures. Further R&D and clinical utility studies are required to determine whether the confirmatory test would be accurate and commercially viable.

According to published reports, there are about 38 million mammograms performed annually in the U.S., resulting in 1.6 million breast biopsies per year. Of these, only 260,000 (16%) result in a cancer diagnosis. The large number of suspicious findings in diagnostic mammograms leads to a significant amount of unnecessary invasive follow-up procedures. The financial burden to the healthcare system imposed by the follow-up testing of false-positive mammograms and breast cancer over-diagnosis is estimated to be $4 billion a year.

About Breast Cancer

Breast cancer is the second most common cancer among US women. Current screening guidelines set forth by the American Cancer Society recommend screening mammography for the early detection of breast cancer in women at average risk. Specifically, guidelines call for annual mammography for asymptomatic women age 45 to 54 and once every two years for women age 55 and older. Suspicious screening mammograms are generally followed up with a diagnostic mammogram and sometimes by an MRI (Magnetic Resonance Image) or an ultrasound. Ultimately, suspicious findings unresolved by imaging typically result in the recommendation of a breast biopsy.

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, Inc.
Matt Haines / Michael Polyviou
917-733-9297 / 212-850-5600
mhaines@evcgroup.com / mpolyviou@evcgroup.com

Financial Media Contact:

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

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