

# ONCOCYTE PRESENTS POSITIVE BLADDER CANCER DIAGNOSTIC DATA AT THE 2016 AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING

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ALAMEDA, Calif., June 06, 2016 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE MKT:OCX), a developer of novel, non-invasive tests for the early detection of cancer, is presenting data today from a bladder cancer study featured as a poster and also highlighted during a live panel discussion during the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

The poster abstract, entitled *Derivation of Gene Expression Classifiers for the Non-invasive Detection of Bladder Cancer in the Hematuria and Recurrence Surveillance Populations*, describes OncoCyte's recent results in the development of a urine-based test for bladder cancer. Dr. Matthew T. Olson, Department of Pathology at Johns Hopkins University School of Medicine, Baltimore, MD, will serve as the presenting author in the live panel discussion. He will be joined by Karen B. Chapman, Ph.D., OncoCyte's Vice President of Research.

"We are very encouraged by the accuracy of our non-invasive test for the detection of high-grade and low-grade lesions in both the screening (hematuria) and recurrence cohorts. Of particular note, the test was 100 percent accurate in detecting high-grade lesions within the 241 patient group studied." said OncoCyte President & Chief Executive Officer William Annett. "There was also high accuracy in the detection of low-grade lesions, with 77 percent for screening and 75 percent for recurrence. The results warrant a larger study to validate these findings."

The detection of bladder cancer is typically accomplished with a combination of cystoscopy and urine cytology, each with inherent limitations. Urine cytology lacks the desired level of sensitivity, whereas cystoscopy is relatively invasive for routine screening and recurrence surveillance.

OncoCyte's study developed four gene expression classifiers (GECs) optimized for the non-invasive detection of both high-grade and low-grade urothelial carcinoma in patients presenting with hematuria or for bladder cancer recurrence surveillance. This study included 241 patient urine samples taken at multiple centers. Individual patient results for high-grade and low-grade screening or high-grade and low-grade recurrence can be obtained from a patient's single urine sample which utilizes two sequential algorithms.

OncoCyte's approach of sequential GECs optimized for the detection of high-grade and low-grade malignancies provides information to distinguish between these different types of lesions and benign conditions in a non-invasive manner. Low-grade urothelial carcinoma is usually a non-aggressive cancer, whereas high-grade urothelial carcinoma is more aggressive, invasive and causes significantly more cancer-related mortality. The GEC optimized for the detection of high-grade urothelial carcinoma in patients presenting with hematuria performed with a cross-validated Receiver Operating Characteristic

Area Under the Curve (ROC AUC) of 0.93, while the low-grade performed with an ROC AUC of 0.81. In the recurrence surveillance cohort, the detection of high-grade performed with an ROC AUC of 0.81 and low-grade with an ROC AUC of 0.64.

#### **ROC AUCs**

	Low Grade	High Grade
Screening (Hematuria)	0.81	0.93
Recurrence	0.64	0.81

"Currently, there is an unmet need for a non-invasive test for bladder cancer for patients requiring recurrence surveillance and for patients presenting with hematuria," added Karen B. Chapman, Ph.D., OncoCyte's Vice President of Research, who led the study. "These results establish the feasibility of using a non-invasive, urine-based test to detect bladder cancer and also to distinguish between high-grade and low-grade cancers. A multicenter clinical trial will allow us to validate test performance on a larger independent test set of prospectively collected urine samples."

### **About Bladder Cancer**

Bladder cancer has been projected to have the highest lifetime treatment costs per patient of all cancers. The high recurrence rate and ongoing invasive monitoring requirements drive the financial burden of this disease. The detection of bladder cancer in hematuria and recurrence patients is routinely accomplished with a combination of urine cytology and cystoscopy which is invasive, and lacks the desired level of sensitivity. Approximately 3 million patients present with hematuria every year in the U.S., of whom about 77,000 are diagnosed with bladder cancer. In addition there are about 587,000 patients in the U.S. living with bladder cancer, and they are candidates for recurrence testing.

## **About OncoCyte Corporation**

OncoCyte is primarily 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**

This press release contains 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") are forward-looking statements. These statements include those pertaining to 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 or regulatory approvals, the need and ability to obtain future capital, 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 as such should be evaluated together with the many uncertainties that affect the business of OncoCyte, particularly those mentioned in "Risk Factors" found in OncoCyte's Securities and Exchange Commission filings. OncoCyte disclaims any intent or obligation to update these forward-looking statements, except as may be required by law.

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