Oncocyte Demonstrates Potential for Liquid Biopsy of Brain Tumors in New Study

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IRVINE, Calif., Dec. 04, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corp. (NASDAQ: OCX), a diagnostics technology company, today announced the publication of favorable data regarding its DetermaCNI™ assay.

In a paper recently published in the journal *Acta Neuropathologica Communications,* DetermaCNI showed promise as a liquid biopsy method for diagnosing and profiling central nervous system tumors by measuring somatic copy number aberrations (SCNAs) in cerebrospinal fluid.

For context, copy number instability (CNI) is a scientifically well-known hallmark of cancer. DetermaCNI™ is a patented approach to measuring CNI for the diagnosis and monitoring of cancer. Nearly 300,000 patients in the U.S. each year face primary brain tumors or brain metastasis[1]. The current standard of care for the confirmation and classification of brain tumors often involves high-risk, highly invasive biopsy of brain tissue. Thus, a liquid biopsy method for diagnosing brain tumors could offer significant benefits over currently available methods, representing a potential $300 million U.S. market opportunity.

Among the study authors were Oncocyte Chief Science Officer Ekke Schuetz and Senior R&D Director Julia Beck.

“This was a proof of principle study to assess whether copy number instability could be measured in the cerebrospinal fluid of patients with brain cancer. The findings suggest that a significant number of the nearly 300,000 patients diagnosed with brain tumors every year in the U.S. could benefit from DetermaCNI,” Dr. Schuetz said. “We congratulate the research team in Frankfurt on the publication of this study in an area of high unmet need.”

As noted in the paper, the gold standard for precise diagnostic classification of brain tumors requires a biopsy, with risks including limited sensitivity and failing to measure the diverse potential regions of the tumor. SCNAs were observed in the cerebrospinal fluid of ten out of the 12 patients with confirmed central nervous system cancers. SCNAs were not observed in any of the 11 patients with benign or unclear central nervous system lesions. The detection of SCNAs is highly specific for tumor-derived cell-free DNA (cfDNA).

Overall, this new study demonstrates DetermaCNI’s potential for providing a molecularly informed diagnosis of central nervous system cancers, mapping tumor heterogeneity, tracking tumor evolution, and surveilling tumor patients through a liquid biopsy of cerebrospinal fluid.

Oncocyte believes this study validates the future clinical potential for DetermaCNI, as well as the direction of the company's research and development pipeline, which is designed to drive sustained rapid growth over the next decade. Oncocyte's mission is to democratize access to molecular diagnostic testing to improve patient outcomes. The company is investing in developing products to serve the separate verticals of organ transplant testing and oncology. Oncocyte is presently commercializing its transplant product line, which includes the VitaGraft™ and GraftAssure™ tests. It expects to commercialize its oncology assays over the next two years.

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1 "Brain Metastases." *MD Anderson Cancer Center*, www.mdanderson.org/cancer-types/brain-metastases.html. And "Brain Tumor Facts." *National Brain Tumor Society*, 20 Feb. 2024, braintumor.org/brain-tumors/about-brain-tumors/brain-tumor-facts/.

About Oncocyte

Oncocyte is a diagnostics technology company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a clinical blood-based dd-cfDNA solid organ transplantation monitoring test. GraftAssure™ is a research use only (RUO) blood-based solid dd-cfDNA organ transplantation monitoring test kit for decentralized use. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. DetermaCNI™ is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients. For more information about Oncocyte, please visit https://oncocyte.com/. For more information about our products, please visit the following web pages:

VitaGraft Kidney™ - https://oncocyte.com/vitagraft-kidney/
VitaGraft Liver ™ - https://oncocyte.com/vitagraft-liver/
GraftAssure™ - https://oncocyte.com/graftassure/
DetermaIO™ - https://oncocyte.com/determa-io/
DetermaCNI™ - https://oncocyte.com/determa-cni/

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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," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, the belief that the new study validates the future clinical potential for DetermaCNI, as well as the direction of the company's research and development pipeline, the expectation that Oncocyte will commercialize its oncology assays over the next two years, and 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 diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions,

obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly 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 (SEC) filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.



Source: OncoCyte Corporation

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