Oncocyte Announces Market Entry and Early Adopter Program for Transplant Rejection Monitoring Business

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Oncocyte enters $2B US transplant monitoring market with newly branded VitaGraft™ patented dd-cfDNA technology in two indications, Kidney and Liver

Oncocyte initiates IVD Kit Development Process with Global Platform Partners, with plans for US FDA submission

IRVINE, Calif., July 13, 2022 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX) today announced that it has completed development and clinical validation of the Laboratory Test for its newly-branded VitaGraft™ Transplant Monitoring tests for Liver and Kidney, entering a $2B US market. The company also opened an Early Adopter Program (EAP) giving access to leading transplant centers prior to a potential CMS coverage decision and full commercial launch. VitaGraft, formerly branded as Therasure™, is a patented, proprietary test built upon the IP acquired in the Chronix Biomedical acquisition last year.

“In less than nine months, we have completed tech transfer, developed and completed clinical validation of the VitaGraft program in both Liver and Kidney, and submitted for Medicare reimbursement,” said Ron Andrews, CEO of Oncocyte. “I’m also pleased to announce that, on a parallel path, we have initiated development of the VitaGraft IVD assay. Our goal is to utilize our patented technology to support better care and faster access to results for patients and physicians in the transplant community. We look forward to giving regular updates on our progress as we anticipate achieving reimbursement and launching our FDA study over the next several quarters.”

VitaGraft has been well-studied across Kidney, Liver, and Heart with over 20 peer-reviewed publications from studies in over 600 patients and over 5,000 samples. The test can serve an important need in managing transplant patients. It is a simple and non-invasive blood test that has been shown to accurately rule-out rejection or injury following transplant with negative predictive values above 97%, helping avoid around 30% of unnecessary biopsies. Furthermore, the test can assist physicians in optimizing dosing of immunosuppressive drugs, to minimize drug related side effects and toxicity.

“We have built a simple workflow that can be automated and potentially provide best in class turnaround time of results,” commented Dr Ekke Schütz, CTO of Oncocyte and former CEO and CMO of Chronix. “I am extremely proud of the R&D and CLIA teams on both sides of the Atlantic for the incredible teamwork to rapidly deliver a test that can have a profound impact on transplant patient management.”

About Oncocyte

Oncocyte is a precision diagnostics company with a mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey.

Through its proprietary tests and pharmaceutical services business, the Company aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. The Company's pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, DetermaCNI™, a blood-based monitoring test, DetermaMx™, a long-term recurrence monitoring test, and VitaGraft™, a blood-based solid organ transplantation monitoring test. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

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, expectations related to Vitagraft, such as the expectation for CMS coverage and reimbursement, the launch of a FDA study over the next several quarters and eventual full commercial launch, 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, the potential impact of COVID-19 on Oncocyte or its subsidiaries' financial and operational results, 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.

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