



Oncocyte's VitaGraft™ Kidney Identifies Transplant Rejection 10 Months Earlier

Sep 18, 2023

Interventional study compares VitaGraft to current transplant rejection monitoring protocols

Oncocyte's VitaGraft assay detects antibody-mediated transplant rejection 10 months sooner than commonly used monitoring protocols (p<0.001)

IRVINE, CA / ACCESSWIRE / September 18, 2023 / [Oncocyte Corporation](#) (NASDAQ:OCX), a precision diagnostics company, today announced the presentation of significant new clinical data at the European Society of Organ Transplant (ESOT) conference.

The data was generated from a randomized interventional clinical trial conducted by Charité, a leading transplant and research institution in Germany. Interim results showed that monitoring kidney transplant patients with Oncocyte's VitaGraft Kidney donor-derived cell-free DNA (dd-cfDNA) assay identified antibody-mediated rejection (ABMR) 10 months sooner than standard of care monitoring protocols.

For DSA+ patients with ABMR, time to diagnosis was significantly shorter in the intervention group than in the control group (3.6 +/- 3.0 vs. 14.1 +/- 1.9 months, p<0.001). This is the first randomized interventional trial demonstrating the superiority of longitudinal monitoring with a dd-cfDNA assay in early identification of ABMR.

The current standard of care uses kidney function tests and other biomarkers to monitor for graft health and AMBR. The data presented at ESOT show that adding longitudinal dd-cfDNA testing like VitaGraft to monitoring protocols has the potential to enable earlier intervention for kidney transplant patients.

"The team at Charité continues to advance the utility of dd-cfDNA testing. We congratulate them on the presentation of these data," said Josh Riggs, CEO of Oncocyte. "We expect that this study and those that follow will lead to improved patient outcomes. These data add to the growing body of evidence supporting VitaGraft's superiority over current monitoring standards to close diagnostic gaps. In addition to detecting ABMR 10 months sooner, VitaGraft can also offer fast turnaround times and absolute quantification."

VitaGraft currently is available as a research use only (RUO) assay upon request. In late August, VitaGraft Kidney received a positive coverage determination from Palmetto GBA, a Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (CMS), confirming that the test has met the criteria for coverage reimbursement under MoIDX: Molecular Testing for Solid Organ Allograft Rejection (L38568). Oncocyte expects to receive pricing information within the next few weeks and to initially commercialize VitaGraft Kidney through its early access program over the next few months. Early

commercial revenue from the test is expected beginning in 1H 2024, with broader commercialization in the U.S. and other countries planned to follow.

ClinicTrials.Gov Link: [NCT04897438](https://clinicaltrials.gov/ct2/show/study/NCT04897438)

More information about the VitaGraft Kidney Test and clinical evidence supporting its use can be found on Oncocyte's website at oncocyte.com/vitagraft-kidney. VitaGraft Kidney is the first in a series of transplant tests in development at Oncocyte. Oncocyte's second transplant test, VitaGraft Liver, remains under review for coverage at MolDX. More information about the VitaGraft Liver Test and clinical evidence supporting its use can be found on Oncocyte's website at oncocyte.com/vitagraft-liver.

About Oncocyte

Oncocyte is a precision diagnostics company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a blood-based solid organ transplantation monitoring test. DetermalO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, and the pipeline test DetermaCNI™ is blood-based monitoring tool for assessing therapeutic efficacy. For more information, please visit: www.oncocyte.com

DetermalO™, DetermaCNI™, and VitaGraft™ are trademarks of Oncocyte Corporation.

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 expectation that this study and additional studies that follow will lead to improved patient outcomes, the anticipation that the Company will receive coverage-related pricing information within the next few weeks for VitaGraft Kidney, Oncocyte's plans to commercialize VitaGraft Kidney through its early access program over the next few months and to begin generating commercial revenue from the test in 1H 2024, expected broader commercialization in the U.S. and other countries, 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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SOURCE: Oncocyte Corporation

via PRISM Mediawire, LLC

