Oncocyte's VitaGraft™ Kidney Used to Monitor Effect of Daratumumab on Antibody Mediated Rejection in New Case Series Study

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Case Series represents second study showing VitaGraft Kidney as a measure of response to the benefit of therapy for one leading cause of allograft failure

IRVINE, Calif., Aug. 12, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corp. (Nasdaq: OCX), a molecular diagnostics technology company, announced the recent publication of a case series of two kidney transplant patients who were monitored for antibody-mediated rejection (AMR) using its proprietary VitaGraft™ Kidney diagnostic test. Patients were tested before, during and after treatment with daratumumab, an anti-CD38 monoclonal antibody[1]. The study underscores the significant potential of using repeated VitaGraft Kidney measurements to monitor the efficacy of anti-CD38 therapy.

VitaGraft Kidney is a noninvasive biomarker[2] that quantifies the concentration of donor kidney DNA in the patient's blood after transplantation. This donor-derived cell-free DNA (dd-cfDNA) test is currently approved by CMS for identifying signs of graft damage in patients with clinical suspicion of rejection.

The case series reports on two patients with biopsy-confirmed chronic active AMR, one of the leading causes of allograft kidney failure, treated with monthly daratumumab infusions and monitored longitudinally with VitaGraft Kidney dd-cfDNA testing. After daratumumab treatment, both patients showed stabilization of kidney function parameters and a steep decline in dd-cfDNA levels below the clinical threshold for rejection. Biopsies six months after treatment demonstrated complete histologic resolution of AMR activity in one patient and partial resolution in the other. The patient with complete resolution showed a significant decline in dd-cfDNA levels to the lower limit of detection, and although the patient with partial improvement in AMR showed slightly higher dd-cfDNA levels, the patient still remained below the rejection threshold.

Today's announcement represents the second publication that shows Oncocyte's ability to monitor therapeutic efficacy. In a recent phase 2 randomized controlled trial published in The New England Journal of Medicine, VitaGraft Kidney was also used to measure the response to another anti-CD38 antibody, felzartamab, for patients with AMR after kidney transplantation. The study noted that dd-cfDNA levels after treatment corresponded to the rejection observed in biopsies at 52 weeks.

"VitaGraft Kidney has high potential to be the most useful biomarker for monitoring the effectiveness of anti-CD38 therapy for AMR," said Dr. Ekkehard Schütz, Oncocyte's Chief Science Officer and one of the authors of both studies. "This test could facilitate not only early diagnosis of AMR but also longitudinal measurements of treatment response and possible post-treatment graft recurrence over the long term."

These new use cases could guide individual management decisions, such as dosing and duration of anti-rejection therapy, while reducing the need for repeated biopsies. By enabling detection, management and monitoring of AMR, VitaGraft could improve graft longevity.

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 presently is commercializing its transplant product line, which includes the VitaGraft™ and GraftAssure™ dd-cfDNA tests. Specifically, GraftAssure is being launched globally with the support of Bio-Rad Laboratories, a leading diagnostics equipment company. Oncocyte received a positive coverage determination from Palmetto GBA, a Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (CMS), for VitaGraft Kidney in 2023.

About Oncocyte

Oncocyte is a molecular 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 solid organ transplantation monitoring test. GraftAssure™ is a research use only (RUO) blood-based solid organ transplantation monitoring test. 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/

VitaGraft™, GraftAssure™, DetermaIO™ and DetermaCNI™ 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, VitaGraft Kidney's potential utility, Oncocyte's ongoing commercialization efforts, 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.

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1 CD38 is a protein found on the surface of many immune cells and targeted in some therapies for cancer. Daratumamab is a targeted cancer drug. Anti-CD38 antibodies such as daratumumab are being studied for the treatment of allograft injury and rejection mediated by immune cells that express CD38, such as natural killer cells in AMR.
2 VitaGraft Kidney measures the amount of DNA in transplant patients’ blood that comes from the donor organ, a key biomarker for assessing graft health. This process is commonly referred to as donor-derived cell-free DNA (dd-cfDNA) testing and is widely used in clinical practice today. Oncocyte has previously demonstrated that VitaGraft Kidney can detect
AMR up to 10 months earlier than current transplant rejection monitoring protocols.

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Source: OncoCyte Corporation