VitaGraft Kidney Expands Utility in Recurrent Primary Disease Patients

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- Blood-based test differentiates between ABMR and IgAN, enabling faster and more effective treatment
- Improved utility over standard of care tests
- Paper published in peer-reviewed journal

IRVINE, Calif., July 25, 2023 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company, today announced the publication of new data demonstrating VitaGraft Kidney's novel ability to help physicians treat kidney transplant patients more precisely, quickly, and effectively. The test was able to distinguish between two prevalent causes of premature graft failure: biopsy-proven antibody-mediated rejection (ABMR) and recurrent IgA nephropathy (IgAN). This is the first publication investigating this application of VitaGraft's donor-derived cell-free DNA (dd-cfDNA) diagnostic technology for kidney transplant patients. The data was published as a paper in the peer-reviewed journal Kidney International Reports.

This ongoing prospective, observational trial evaluated VitaGraft Kidney's dd-cfDNA diagnostic technology as a tool to discriminate between recurrent IgAN and ABMR. In the study, VitaGraft Kidney demonstrated higher sensitivity and specificity for detection of ABMR over routine tests (eGFR, uACR, DSA). Differentiating between recurring IgAN and ABMR could help physicians select the appropriate treatment for the patient more quickly, while potentially also avoiding unnecessary procedures and treatments. In the paper, the authors highlight the limited value of currently marketed tests for the identification of treatable early-stage ABMR and suggest that dd-cfDNA testing could be a useful longitudinal management tool.

"This is an important study for clinicians because we now have a precise and noninvasive tool to better discriminate ABMR from other causes of kidney injury," said Prof. Klemens Budde, MD, head of kidney transplantation in the Department of Nephrology at Charité Universitätsmedizin Berlin, which runs the largest transplant program in Germany.

"I am excited by the outcome of this blinded study in a biopsy-controlled kidney transplantation cohort. The fact that our dd-cfDNA assay outperformed the established biomarkers used in the study for comparison is an important outcome for patient care," said Ekke Schuetz, MD, PhD, CSO of Oncocyte.

The application of dd-cfDNA testing in post-transplant patients represents a $2B market. Oncocyte has submitted its dd-cfDNA tests VitaGraft Kidney and Liver for Medicare reimbursement and expects its next feedback from Palmetto, which administers the MolDx Program, within 30 days.

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, DetermaIO™ 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 monitoring therapeutic efficacy in cancer patients.

VitaGraft™, 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, the expectation that the Company will receive feedback from MolDx within 30, 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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