Favorable Oncocyte VitaGraft Kidney Study Results Published in the New England Journal of Medicine

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- Late-breaking presentation of data at American Transplant Congress on Monday, June 3
  - Data show potential to monitor for therapeutic efficacy and recurrence
    - Potential repeat testing opportunities with claims expansion

IRVINE, Calif., May 30, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company, today announced that favorable data regarding its lead product VitaGraft™ Kidney was published in the New England Journal of Medicine. Oncocyte's Drs. Ekke Schuetz and Julia Beck, inventors of the technology, are among the authors of the study. VitaGraft Kidney was used to monitor graft injury in a phase 2 double-blind, placebo-controlled study (NCT05021484) of the investigational drug felzartamab, a fully human CD38 monoclonal antibody, for antibody-mediated rejection (AMR), a leading cause of kidney allograft failure.

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. In this study, Oncocyte's proprietary diagnostic test using droplet-digital PCR was able to identify responders and non-responders to felzartamab, showing, "a decrease in dd-cfDNA fractions at week 12 (0.33% [0.25−0.40] versus 0.95% [0.37−1.63]; mean difference: −0.75%; 95% CI: −1.41, −0.09) and week 24 (0.31% [0.21−0.49] versus 0.82% [0.34−2.90])."

The study points to new clinical utilities for VitaGraft Kidney beyond the Company's currently approved and reimbursed indication of *for cause* testing. Both therapeutic efficacy and recurrence monitoring are potential new use cases for dd-cfDNA testing. Both utilities would be expected to require multiple tests during the active management phase, when a drug is being given, and long-term to help doctors watch for AMR recurrence.

"The results of the phase 2 trial suggested that monitoring of dd-cfDNA could be useful to accurately detect responsiveness to felzartamab therapy, also uncovering disease recurrence after stopping treatment," said Dr. Georg Böemig, Medical University of Vienna, senior author of the publication. "Therefore, the assay could have high potential as a tool to individually guide dosing intervals and duration of anti-rejection therapy."

Up to 20.2% of kidney transplant patients will develop AMR within 10 years of transplant and up to 70% of those patients will progress to graft failure.[1] Currently, there are no FDA approved drugs that have indications for the management of AMR. Results of the phase 2 trial suggest that the combination of

felzartamab drug therapy and VitaGraft Kidney testing may have significant potential to address this key unmet need in transplant management by enabling detection, management, and monitoring of AMR.

“We congratulate the research teams on this groundbreaking study and its potential to lead to a treatment option for kidney transplant patients suffering from AMR around the world,” said Josh Riggs, Oncocyte CEO. “We are grateful for the support from our research partners and their inclusion of our test in this study. It is exciting to see a new opportunity for Oncocyte’s technology to serve the clinical market and patients in need. This study, combined with earlier results showing that our test can detect AMR up to 10 months earlier than protocol, points to new opportunities to improve care and outcomes for these high-risk patients. In the future, we expect that VitaGraft will be there to support physicians looking to detect AMR as early as possible and then effectively manage this disease.”

“Our recent partnership with Bio-Rad, gives us the scale we need to support the global transplant research community with easy-to-use dd-cfDNA monitoring tools,” continued Mr. Riggs. “Use cases like this will help drive adoption of our combined technology around the world.”

The results of this publication will be discussed as a Late Breaking Abstract at the 2024 American Transplant Congress on June 3rd 2024 at 9:15 ET by Dr. Katharina Mayer from the Medical University of Vienna. Oncocyte will be exhibiting at the conference at Booth #430.

Oncocyte will be hosting a conference call to discuss the results of the clinical trial with study authors, Dr. Klemens Budde, Head of Transplantation at Charite, and Dr. Ekke Schuetz, Chief Science Officer at Oncocyte. Dr. Schuetz developed the dd-cfDNA technology as CEO and CSO of Oncocyte subsidiary Chronix Biomedical alongside Dr. Julia Beck. The clinical presentation will be followed by an operational update and Q&A focused on the commercial launches of VitaGraft Kidney and GraftAssure by Josh Riggs. Investors may submit questions for the Q&A by emailing them to the contact information listed below. The date and time of the call will be announced in due course.

[1] Mujtahedi, S.S., Yigitbilek, F., Ozdogan, E. et al. Antibody-Mediated Rejection: the Role of Plasma Cells and Memory B Cells. Curr Transpl Rep 8, 272–280 (2021). https://doi.org/10.1007/s40472-021-00342-1

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 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/

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About Antibody-Mediated Rejection (AMR) in Kidney Transplant Recipients

Antibody-mediated rejection (AMR) is a major cause of kidney transplant failure, with late AMR affecting approximately 23,000 patients total in the U.S. There is no effective treatment for AMR and patient options are highly limited. Donor-specific antibody (DSA) production by plasma cells, and tissue infiltration of Natural Killer (NK) cells presumed to be involved in DSA-dependent microvascular inflammation, are both linked to AMR. Observations that both plasma cells and NK cells express high levels of CD38 have motivated the approach of targeting CD38 to deplete these cell populations to address AMR.

About Felzartamab

Felzartamab is an investigational therapeutic human monoclonal antibody directed against CD38, a protein expressed on mature plasma cells. Felzartamab has been shown in clinical studies to selectively deplete CD38+ plasma cells, which may allow applications that ultimately improve clinical outcomes in a broad range of diseases driven by pathogenic antibodies. Felzartamab is an investigational therapeutic candidate that has not yet been approved by any regulatory authority.

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 future of VitaGraft Kidney, the anticipation that Oncocyte and Bio-Rad's combined technology will be adopted around the world, 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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