Oncocyte's Proprietary Assay Demonstrates Long-Term Clinical Validity

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Transplantation Direct publication uses assay to identify rejection in patients up to 13 years post-transplant

- Robust data set of 131 patients with 151 kidney biopsies enrolled over four years at Charité University in Berlin
- Supports market expansion for testing of high-risk patient population
- New findings advance understanding of the biology of organ rejection

IRVINE, Calif., April 29, 2025 (GLOBE NEWSWIRE) -- Oncocyte Corp., (Nasdaq: OCX), a leading diagnostics technology company, today announced the publication of new and positive data regarding its proprietary blood-based transplant rejection assay. The publication, "Association of Blood Donor-derived Cell-free DNA Levels with Banff Scores and Histopathological Lesions in Kidney Allograft Biopsies: Results From an Observational Study," is co-authored by Oncocyte's Drs. Ekke Schuetz and Julia Beck, inventors of the technology. Findings from the study bode well on both a strategic level for Oncocyte as well as on a scientific level for the transplant industry.

Scientifically, Oncocyte's test is being used to help study the biology of organ rejection. The study revealed a correlation between microvascular and vascular inflammation and elevated dd-cfDNA in the blood plasma, contributing to the broader understanding of the pathophysiology of the analyte. Two novel observations from the study are described in more detail below, under "Scientific significance". Strategically, the study highlights the opportunities for market expansion to monitor high-risk patients over the long-term.

"There are only a few publications on the dynamics of dd-cfDNA in other common pathologies beyond rejection," said Oncocyte Chief Science Officer Dr. Schuetz. "Our study aimed to assess both the absolute and relative values of dd-cfDNA in diverse histopathological patterns, the correlation of dd-cfDNA with Banff lesion scores, and the recently suggested Banff-based activity and chronicity indices in consecutive cases of kidney transplant recipients undergoing indication biopsies."

Oncocyte is at a pivotal stage in commercializing a potentially industry-transforming organ-transplant-rejection-monitoring test. The company aims to deliver proven, more affordable, faster tests that can be run at local labs. Specifically, Oncocyte is developing a kitted test that quantifies dd-cfDNA and plans to commercialize that technology using a market disruptive approach. In addition to developing a kitted version of its assay, Oncocyte also offers a dd-cfDNA-detection assay at its Nashville laboratory, which achieved Medicare reimbursement in August 2023.

"This latest publication comes from a long-standing research and collaborative relationship that we have with Charité University in Berlin, one of the leading research universities in the world," Oncocyte CEO,

Josh Riggs, said. “As they continue to advance the field’s scientific knowledge about transplantation, we are proud that our assay is being used to understand the fundamental biology at play in transplanted organ rejection.”

Strategic significance: Market expansion

This study builds upon the scientific foundation that supports long-term and aggressive management of high-risk patients, utilizing Oncocyte’s proprietary test.

First, the study’s size and duration validate that Oncocyte’s proprietary assay remains a clinically valid way to measure transplant health over the long term. Patients in the study were between 1.6 years to 13.7 years post-transplant. This means that over a decade into patient management, researchers were still seeing utility in dd-cfDNA testing.

Second, a significant percentage of the patients in the study with proven transplanted organ rejections also had *de novo* donor-specific antibodies (dnDSA+) in their blood. These types of patients are the same high-risk patients that Oncocyte identified in its groundbreaking prospective, randomized clinical trial study that was published in 2024, leading to Medicare reimbursement coverage expansion for claims in 2025.

“Data from this study reinforces that doctors should be routinely screening these high-risk patients with our test,” Mr. Riggs added. “Kidney transplant management is changing. Anti-CD38 therapies have a chance at treating transplant rejection. Assuming the data continue to be supportive, catching transplant rejection as early as possible becomes critical.”

Scientific significance: Novel observations

Two observations from the study are novel: 1) T-cell mediated rejection (TCMR) is associated with a high elevation of dd-cfDNA if vascular inflammation (vi) is present and 2) Calcineurin inhibitor (immunosuppressive medications) toxicity does not lead to an increase in dd-cfDNA levels.

In summary, dd-cfDNA seems to be a relatively specific biomarker for rejection, both antibody-mediated rejection (ABMR) and TCMR with vi. Why certain patients with BK virus infection also encounter an elevation of dd-cfDNA is currently under investigation.

Full Citation:

Akifova, Aylin MD1; Budde, Klemens MD1; Choi, Mira MD1; Amann, Kerstin MD2; Buettner-Herold, Maike MD2; Oellerich, Michael MD3; Beck, Julia PhD4; Bornemann-Kolatzki, Kirsten PhD4; Schütz, Ekkehard PhD4; Bachmann, Friederike MD1; Halleck, Fabian MD1; Schrezenmeier, Eva V. MD1; Seelow, Evelyn MD1; Zukunft, Bianca MD1; Hammett, Charlotte MD1; Pohl, Nathan A.1; Mordà, Benedetta MD1,5,6; Kowald, Jan MD7; Lachmann, Nils8; Stauch, Diana8; Osmanodja, Bilgin MD1. Association of Blood Donor-derived Cell-free DNA Levels With Banff Scores and Histopathological Lesions in Kidney Allograft Biopsies: Results From an Observational Study. Transplantation Direct 11(5):p e1794, May 2025. | DOI: 10.1097/TXD.0000000000001794

Link to study:
https://journals.lww.com/transplantationdirect/fulltext/2025/05000/association_of_blood_donor_derived_cell_free_dna.9.aspx

About Oncocyte
Oncocyte is a pioneering diagnostics technology company whose mission is to democratize access to

novel molecular diagnostic testing to improve patient outcomes. Investors may visit https://investors.oncocyte.com/ for more information.

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, Oncocyte's progress toward commercializing a potentially industry-transforming organ-transplant-rejection-monitoring test , 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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