Oncocyte Signs Leading Transplant Centers in US and Germany

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- GraftAssure™ research assay adopted by two research hospitals that are top-five-in-country by organ transplant volume
- Company clears first stage gate in clinical product development process and has submitted a Q-Sub to the FDA

IRVINE, Calif., Oct. 02, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX) ("Oncocyte" or the "Company"), a diagnostics technology company, today announced that its new customers include two leading transplant university hospitals in the U.S. and Germany. Both have entered into agreements with the Company to utilize GraftAssure™, the Company's research-use-only assay ("GraftAssure") that can detect early evidence of graft organ damage in patients' blood.

Oncocyte believes that it is at a pivotal stage in commercializing its intellectual property in organ transplant, primarily by making a kitted test that relies upon a biomarker, donor-derived cell-free DNA (dd-cfDNA). Today's announcement serves as important validation of the Company's continued momentum.

Providing research centers access to GraftAssure is a key part of the Company's "land-and-expand" strategy to drive commercial adoption of its molecular diagnostic tests and to capture market share in an estimated $1 billion transplant addressable market. Oncocyte plans to partner with major transplant centers and research universities with its research-use-only product, GraftAssure. If the Company achieves Food and Drug Administration ("FDA") clearance for its test kits to be used for clinical decisions, or clearance as an in-vitro diagnostic ("IVD"), the Company believes that institutions will begin using its tests to manage their patient populations. It is important to note, however, that GraftAssure is not a clinical product and is intended for research use only.

"We are thrilled with the market response to GraftAssure," said the Company's Chief Executive Officer, Joshua Riggs. "The two institutions located in the U.S. and Germany that we have entered into agreements with are well-regarded major research hospitals that are top-five centers in their respective countries. We believe these institutions share our vision of democratizing access to this molecular diagnostic technology."

Oncocyte also announced that it is on track and has submitted its plan for an IVD version of its dd-cfDNA kitted test to the FDA, beginning the Q-submission process. A meeting with the FDA is scheduled for early December in connection with the submission. This is a formal pathway for companies to get written feedback on their development plan and a critical step in gaining confidence for the validation process the Company expects to begin in early 2025.

The number of institutions expressing interest in the Company's transplant assay has exceeded management's expectations, and the Company is converting this interest into committed customers. In August 2024, Oncocyte reported that its GraftAssure assay had been run at a major metropolitan transplant center and research university in the northeast U.S. as well as a lab at a leading transplant center in Southeast Asia.

Since August 2024, additional transplant centers have committed to adopting GraftAssure, including the previously referenced university hospitals in the U.S. and Germany.

Oncocyte continues to work to establish a customer base to support future revenue growth. Its first prototypes of GraftAssure were completed in December 2023, and by April 2024, Oncocyte welcomed Bio-Rad Laboratories, Inc. ("Bio-Rad") as an investor and strategic partner, supporting GraftAssure's global launch. Under this partnership, Bio-Rad and the Company are co-marketing GraftAssure in the US and Germany, with the Company acting as commercial lead in those markets. Bio-Rad has exclusive distribution and commercial rights outside the US and Germany.

The transplant market is highly concentrated with fewer than 100 academic and research centers in the U.S. that account for approximately 80% of transplant volumes. Markets outside the U.S. are similarly concentrated within high-end academic institutions. Bio-Rad's global infrastructure puts those centers well within reach, allowing for high-touch sales and service in those regions.

About Oncocyte

Oncocyte Corporation 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 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 a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients. For more information, visit https://oncocyte.com/

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, future expansion and growth, plans to have transplant centers running GraftAssure tests through the end of 2025, assumptions regarding regulatory approvals and clearances, timing and planned regulatory submissions, 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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