Oncocyte Provides Positive Update on Clinical Trial Progress

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- *Central Institutional Review Board approved, final preparatory steps underway at first transplant centers*
- *Three of the top 10 U.S. transplant centers expected to participate in trial*
- *Nearly 10% of annual U.S. transplant volume represented in trial site interest*
- *Preparing for final Q-sub FDA meeting ahead of clinical validation*

IRVINE, Calif., April 30, 2025 (GLOBE NEWSWIRE) -- Oncocyte Corp., (Nasdaq: OCX), a leading diagnostics technology company, today provided a positive update on its substantial progress toward initiating its clinical trial, which is a major step required to obtain regulatory authorization to deliver an organ transplant rejection monitoring test kit to the market.

Oncocyte has completed its clinical trial design and has received approval from a large central institutional review board (IRB), which is a committee that reviews and oversees the safety and ethics of clinical trials across multiple hospital sites.

Within the coming weeks, Oncocyte expects to welcome three of the top 10 transplant centers in the United States as clinical trial participants. The U.S. transplant centers engaged in supporting Oncocyte's clinical trial collectively represent nearly 10% of U.S. transplanted organ volume. The company values the clinical expertise and diverse patient populations that these leading transplant centers contribute to the trial.

Oncocyte estimates that transplant rejection testing generates about $500 million in revenue per year in the U.S., largely dominated by a few central labs. U.S. regulatory authorization of Oncocyte's kitted test would enable transplant centers to perform this testing locally in their own labs, thus generating revenue for themselves and increasing the sustainability of local care for the community. Globally, Oncocyte estimates that the total addressable market for transplant rejection testing exceeds $1 billion annually.

"The transplant community has been energized by the opportunity to bring testing in-house. Some of the largest transplant centers in the U.S. are signing up to help us get our kit to market. We are thrilled with their support," Oncocyte CEO Josh Riggs said. "We have several milestones ahead of us that we look forward to communicating to the market."

"When we announced our partnership with Bio-Rad in April 2024, it was with this moment in mind," Mr. Riggs continued. "We're building nice momentum heading into the trial and continue to target submission of our data package in the second half of this year."

In the coming weeks, the company plans to announce the identity of its National Principal Investigator (NPI), a leading transplant specialist, and host a conference call to introduce this key opinion leader to the medical and investor communities.

Importantly, the upcoming clinical trial is the only one required to obtain FDA authorization for Oncocyte to bring its first test kit to market. For clarity, Oncocyte is pursuing a Class II *de novo* pathway – a regulatory route for lower-risk medical devices. Class II medical devices carry lower risk than Class III devices, which are typically life-supporting technologies. The company has already achieved CLIA validation and reimbursement of the lab-developed version of the test with Centers for Medicare & Medicaid Services (CMS).

Additionally, Oncocyte also announced that in the coming weeks it expects to complete its second and final Q-Submission (Q-Sub) meeting, which is a formal process for requesting feedback from the FDA before applying for product authorization. Oncocyte's first Q-Sub meeting in December and subsequent conversations have remained productive, featuring collaborative dialogue with FDA reviewers.

"We are pleased with the quality of the engagement we've had with the FDA so far and are looking forward to our final Q-Sub meeting," said Dr. Johnson Chiang, Chief Technology Officer of Oncocyte. "This process, combined with the quality of our clinical trial, reflects the strong foundation we are building for FDA submission and authorization."

Oncocyte's kitted test quantifies a molecular biomarker known as donor-derived cell-free DNA (dd-cfDNA). The company's scientists in Germany and the U.S. have played a critical role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of transplant rejection, and the company is now commercializing that technology using a market disruptive approach.

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 initiating its clinical trial, the quality and breadth of the clinical trial and Oncocyte's anticipated position as a differentiated partner in the transplant diagnostics market, expected regulatory approval(s) and submission(s) and the timing of such approval(s) and submission(s), milestones to be communicated to the market, anticipated announcement of Oncocyte's NPI, the expectation that Oncocyte will complete its second and final Q-Sub meeting with the FDA in the coming weeks, Oncocyte's plans to sell test kits to hospital labs, 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.

Investor Contact:

Doug Farrell
LifeSci Advisors LLC
dfarrell@lifesciadvisors.com

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