Medicare Boosts Reimbursement for Oncocyte's Flagship Technology

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- New price of $2,753 for the GraftAssureCore™ assay increases total addressable market size and margin opportunity
- Brings pricing in line with existing competitive technology
- Expands market appeal for prospective FDA-cleared kitted product at transplant centers

IRVINE, Calif., May 19, 2025 (GLOBE NEWSWIRE) -- Oncocyte Corp., (Nasdaq: OCX), a diagnostics technology company, today provided a positive update on pricing for its next-generation lab-developed test (LDT), GraftAssureCore. The new reimbursement rate strengthens the company's position in the growing transplant rejection testing market and suggests potential upside to its estimated $1 billion total addressable market.

The Centers for Medicare & Medicaid Services (CMS) has improved its reimbursement rate to $2,753 per result. This represents an increase from the prior structure using an earlier version of the assay, which paid $2,222 for first-time testing of a patient and $1,029 for subsequent tests. GraftAssureCore[1] is Oncocyte's lab-developed test (LDT), which is run at the company's CLIA-certified Nashville lab[2].

"Over the past two years Oncocyte has made significant investments in improving the scalability and manufacturability of our workflow to support our kitted test program," said CEO, Josh Riggs. "Last fall, we transferred these improvements into our CLIA lab and submitted to MolDX[3] for repricing. We are very pleased with the result."

The new rate for the optimized workflow sets a benchmark that can be used to establish a reimbursement pathway for its future kitted test, GraftAssureDx, which the company expects to submit for FDA review by the end of this year. This process, known as "bridging," would allow other labs, upon receipt of FDA marketing authorization by Oncocyte, to purchase the Oncocyte kits to perform the test themselves and bill Medicare at the same rate.

"We believe this new price reflects the value that our technology brings to the transplant community," continued Mr. Riggs. "Once we receive FDA authorization, the ability to run the test clinically and bill Medicare directly will drive much broader adoption of our technology. We look forward to providing transplant centers the opportunity to access a high-quality, FDA-cleared kit with established reimbursement."

"We are very excited about the future of our company and this technology," said Chief Science Officer Dr. Ekke Schuetz. "We believe that our activation of decentralized testing will enable broader use of dd-cfDNA, transforming it from a high-cost technology to a revenue generating solution for transplant institutions."

Oncocyte provided a positive update on its FDA submission process and clinical trial in an announcement on April 30. The company noted that a Central Institutional Review Board approved its clinical trial, that final preparatory steps are underway at the first participating transplant centers, that it expects three of the top 10 U.S. transplant centers to participate in its trial, and that nearly 10% of annual U.S. transplant volume is represented in clinical trial site interest.

Footnotes:

(1) Oncocyte's flagship technology 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. Per recent rebranding announcements, *GraftAssure* is becoming the umbrella brand for the company's dd-cfDNA test portfolio. The company is in the process of rebranding its VitaGraft assay (also known as VitaGraft Kidney), which is a lab developed test, under the name GraftAssureCore. For purposes of this press release, references to "GraftAssureCore" shall be deemed to include the test previously marketed as VitaGraft. The company is also in the process of rebranding its research-use-only (RUO) test kit, GraftAssure, as "GraftAssureIQ," and rebranding its future *in-vitro* diagnostic (IVD) test kit as "GraftAssureDx."
(2) CLIA, or the Clinical Laboratory Improvement Amendments, is a federal program overseen by CMS that ensures laboratories meet quality standards when performing diagnostic testing on human samples.
(3) MolDX is a program managed by Medicare contractor Palmetto GBA (Government Benefits Administrators) that reviews molecular diagnostic tests and decides whether they should be covered and reimbursed by Medicare.

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 commercial progress, anticipated FDA submissions, the expectation that Oncocyte will receive FDA marketing authorization for GraftAssureDx, the belief that decentralized testing will enable broader use of dd-cfDNA, transforming it from a high-cost technology to a revenue generating solution for transplant institutions, the expectation that three of the top 10 U.S. transplant centers will participate in Oncocyte's trial, 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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