Oncocyte Begins FDA Submissions Process for VitaGraft Transplant Assays

- Significant unmet need for regulated product in $2B US testing market
- Opportunity for expedited pathway for kitted product in development

IRVINE, Calif., December X, 2023 -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company, today announced it has begun the FDA single-site process for its VitaGraft transplant assays. The single-site process is a well-established pathway for Lab Developed Tests (LDTs) to seek regulatory approval. This move positions Oncocyte within the recent proposed rule from the FDA that seeks to oversight LDTs and puts its lab-developed tests and kitted products on parallel paths.

“Establishing our VitaGraft Assay Lab Developed Test as a regulated device is good for patients and is a key part of our regulatory strategy,” said Josh Riggs, CEO of Oncocyte. “With minimal incremental investment, we can take a big step forward. If we are successful, it potentially creates what is known as a predicate device. Having a predicate in place can significantly reduce the time and complexity of follow-on submissions to the FDA. We hope to use this pathway when it is time to submit our kitted product.”

“Ultimately, we believe that FDA clearance will be a significant competitive advantage for us in the multi-billion-dollar transplant testing market and will drive adoption beyond the estimated 25-30% we see today. We look forward to working with the FDA to bring our technology forward.”

The Company recently announced a positive coverage decision from MolDX at the end of August 2023 for its Kidney indication, which is expected to launch commercially in the first half of 2024.

The FDA Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request (De Novo request). This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA’s mission to protect and promote public health.

On September 29, 2023, the FDA announced this proposed rule: Medical Devices; Laboratory Developed Tests. The proposed rule seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. Under the FDA’s proposed rule, laboratory-developed tests would be classified as medical devices and subject to premarket clearance and/or approval.

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 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 blood-based monitoring tool for assessing therapeutic efficacy. For more information, please visit: www.oncocyte.com

DetermaIO™, DetermaCNI™, and VitaGraft™ 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, the anticipated final rule from the FDA, the Company's hope that it will be successful in establishing its VitaGraft Assay Lab Developed Test as a regulated device, potentially creating a predicate device, the possible reduction in time and complexity of follow-on submissions to the FDA and Oncocyte's plans to use this pathway when it is time to submit its kitted product, the belief that FDA clearance will be a significant competitive advantage, the anticipated commercial launch of Oncocyte's Kidney indication in the first half of 2024, 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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