Oncocyte Completes Validation of TheraSure™ Transplant Monitor Test

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Digital PCR format allows for rapid turnaround time to facilitate fast and accurate post-transplant treatment decisions

IRVINE, Calif., May 05, 2022 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company with the mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey, today announced that it has completed development of its proprietary TheraSure™ Transplant Monitoring test for liver transplant patients. This announcement marks the successful completion of technology transfer and Oncocyte's readiness to deploy TheraSure following the Company's acquisition of Chronix Biomedical.

"Today's announcement marks the first product to be launched clinically from our Chronix acquisition completed in April 2021. The tech transfer of the proprietary blood based technology used to develop TheraSure was an important undertaking for our R&D team in Germany and our CLIA lab team in Nashville, and I am extremely proud of the herculean effort put forth to meet the aggressive timeline we set last year to put us in a position to launch the liver indication in the first half of 2022," said Ron Andrews, President and CEO of Oncocyte. "Management believes that the streamlined workflow developed by our two expert PCR development teams paves the way for expedited validation of TheraSure for kidney and heart transplants and prepares the Company for the important work ahead to convert the lab workflow into a kit."

The TheraSure Transplant Monitor, a donor-derived cell-free DNA (dd-cfDNA) test which has shown to successfully achieve an early indication of rejection episodes in organ transplant patients using a digital polymerase chain reaction (dPCR) technique, may allow for timely post-transplant treatment modification to prevent organ damage. Oncocyte's patented test has been validated in clinical cohorts that have been published in kidney, liver and heart transplantation.

"The anticipated speed and accuracy of dPCR testing, particularly the proprietary TheraSure Transplant Monitor test, are important attributes of our technology. We are thrilled to enable access of this test through our laboratory offering, meeting a truly unmet need for liver transplant patients and their physician care teams that is backed by peer-reviewed and published data," said Ekkehard Schutz, MD, PhD, FAACC, CTO and Head of Blood Based Testing at Oncocyte. "Today, there is no other alternative test for liver transplant patients, and I am proud of the lab team's efforts to develop a workflow that can meet the goal of same day turnaround time of results once the blood sample is accessioned into our lab. Based on the successful validation of our dPCR workflow for TheraSure, we believe we can provide these results to certain transplant labs within one or two days of receipt of the blood sample to inform timely, critical medical decisions."

About Oncocyte

Oncocyte is a precision diagnostics company with a mission to improve patient outcomes by providing

personalized insights that inform critical decisions throughout the patient care journey.

The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage post-diagnosis treatment. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research-use only tool, assesses the tumor microenvironment to predict response to immunotherapies. The Company's pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, blood-based test DetermaCNI™, which can monitor cancer patients for recurrence of disease, long-term recurrence monitoring test DetermaMx™, and blood-based solid organ transplantation monitoring test TheraSure™. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx™, DetermaIO™, DetermaTx™, DetermaCNI™, DetermaMx™ and TheraSure™ 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, TheraSure, such as the expectation of expedited validation of TheraSure for kidney and heart transplants and of conversion of the lab workflow into a kit, 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.

Investor Contact
Caroline Corner
ICR Westwicke

415.202.5678
Caroline.corner@westwicke.com

Media Contact
Megan Kernan
ICR Westwicke Healthcare PR
Tel: 646.677.1870
Megan.kernan@westwicke.com

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