Medicare Coverage Determination for Molecular Testing Announced for Solid Organ Allograft Rejection, Citing Multiple Publications from OncoCyte Corporation's Subsidiary Chronix Biomedical, Inc.

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Coverage policy for transplant rejection monitoring establishes a simplified and accelerated pathway for Medicare coverage of Chronix's solid organ transplant rejection monitoring test

Oncocyte's newly acquired IP creates solid foundation for blood-based monitoring for cancer recurrence as well as establishes differentiated, patented product offering for potential partner in $3.5B Global Transplant Rejection Diagnostic Market

IRVINE, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, announced that that a pathway for future Medicare reimbursement coverage may have been created for TheraSure™ Transplant Monitor, a solid organ transplantation monitoring test developed by Oncocyte's subsidiary Chronix Biomedical, Inc. The Chronix monitoring test is intended to use a simple blood draw to monitor for rejection of transplanted organs.

Palmetto, the Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (CMS), issued a local coverage determination (LCD) recognizing molecular testing for solid organ allograft rejection as a category of tests eligible for Medicare reimbursement. This policy extends coverage to any method providing donor derived cell-free DNA (dd-cfDNA) values with proven analytical performance. The decision establishes a simplified and accelerated pathway for Medicare reimbursement coverage that Oncocyte's new subsidiary Chronix may follow for its patented solid tumor organ transplant rejection monitoring technology.

The coverage policy for transplant rejection monitoring,
Molecular Testing for Solid Organ Allograft Rejection, cites three peer reviewed publications on the performance of the Chronix test in solid organ transplant monitoring, and establishes a pricing parameter of $2,700 to $2,800 per test depending on the organ transplanted. Oncocyte estimates that total revenues could range from $40,000 to $50,000 per patient over a two-to-three year timeframe assuming current transplant monitoring guidelines are followed. The Chronix TheraSure™ Transplant Monitor test is unique in that it has been validated in clinical cohorts after kidney[1], heart[2] and liver[3] transplantation. It is also the only patented assay available for dd-cfDNA that reveals absolute cfDNA concentrations in addition to percentage values. Peer reviewed journals and numerous studies have established that absolute concentration data are superior to percentage value data in rejection detection[1] in kidney and eliminate a systematic bias seen in competing technologies used to test organ rejection in patients later than one year after transplant[4].

Ron Andrews, President and Chief Executive Officer of Oncocyte said, “We are very excited about the recent decision by CMS to award high value reimbursement determination for this important class of transplant monitoring tests. More importantly, the exclusive inclusion of the Chronix papers in the LCD highlights the value of the technology we now own and plan on using as the foundation to expand our product development efforts into blood-based monitoring for cancer. While Oncocyte’s focus remains oncology, given this simplified and accelerated path to CMS coverage, as well as important product attributes like greater sensitivity, reduced cost to run and the ability to kit and democratize the monitoring test to improve turnaround times, we believe that we have a very attractive asset which could be desirable to both current and new players in the Transplant Diagnostic market in the United States and EU.”

With approximately 40,000 transplants in the U.S. annually, and approximately the same amount in the EU, Oncocyte estimates that the total addressable market is around $2 billion in the US, and globally around $3.5 billion. Approximately 65% of transplants are kidneys, 25% heart and 10% liver, and the Chronix test cited has data to support use in all three major organ categories.

“This policy recognizes dd-cfDNA as a non-invasive rejection test based on demonstrable substantial equivalence to existing tests,” said Dr. Ekkehard Schütz, FAACC, General Manager and Chief Medical Officer of Oncocyte Europe. “This equivalence has already been established for the Chronix test, as reflected in articles published in peer-reviewed publications cited in the new CMS coverage determination*. We believe that our approach which focuses on a same-day turnaround time for improved test performance as well as the addition of dd-cfDNA concentrations values in testing results will provide the most valuable and accurate view on the health of the transplanted organ through the entire life of the organ.”

Michael Oellerich, MD, Hon MD, FAACC, FAMM, FFPath (RCPI), FRCPath, chemical pathologist, Distinguished Research Professor at the Department of Clinical Pharmacology, University Medical Center of the George-August-University Göttingen, Germany, Oncocyte’s scientific advisor for transplantation and a world leading authority in the field, commented on the importance of dd-cfDNA, stating that, “It has been documented in more than 50 studies that dd-cfDNA detects rejection early at an actionable stage. In addition to detecting rejection, it reflects the severity of graft injury from rejection. When rejection is caught early it may be possible to arrest rejection damage to the transplanted organ by implementing a personalized immunosuppression course of treatment[5] for the patient which ultimately can extend the life of the transplanted organ.”

About Oncocyte Corporation

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company’s tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection, and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™ in the second half of 2021 as a test to assess mutational status of a tumor to help identify the appropriate targeted therapy. The Company recently completed the acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor (to be rebranded as DetermaCNI) and TheraSure™ Transplant Monitor test, which are both available for clinical research use in EU, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based

monitoring market. Oncocyte's pharmaceutical services provide a full suite of molecular testing services to support the drug development process for pharmaceutical companies that are developing new cancer treatments.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation, and TheraSure™ is a trademark of Chronix Biomedical, Inc.

Oncocyte Forward Looking Statements. Oncocyte cautions you that this press release contains 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 the Chronix TheraSure™ CNI Monitor test, including its potential use and efficacy, the potential for Medicare reimbursement and pricing, potential addressable market sizes, 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 our or our 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 our 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, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we or our subsidiaries commercialize, 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 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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graft damage marker in liver transplantation: A prospective, observational, multicenter cohort study. PLoS Med. 2017;14(4):e1002286

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4	Schütz, E. *et al.* Time-Dependent Apparent Increase in dd-cfDNA Percentage in Clinically Stable Patients Between One and Five Years Following Kidney Transplantation. *Clinical chemistry***66**, 1290-1299, doi:10.1093/clinchem/hvaa175 (2020).
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Source: Oncocyte Corporation