



## Oncocyte Announces Unanimous Recommendation from the Advisory Panel for Clinical Diagnostic Laboratory Tests on DetermaRx to CMS

Sep 07, 2022

### **Palmetto GBA Conveys Validity of Broader Claim for DetermaRx As a Risk of Recurrence Test Expanding Market Utility**

IRVINE, Calif., Sept. 07, 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 the Advisory Panel for clinical diagnostic laboratory tests (CDLT) has unanimously recommended that starting January 2023, the Company's DetermaRx™ test be cross-walked to CPT code 81522, currently priced at \$3,873. Medicare (CMS) will consider this recommendation and is expected to post its preliminary decision in mid-September for public comments and issue a final determination in mid-November.

Separately, the Company announced that Palmetto GBA, a Medicare administrative contractor for the Molecular Diagnostics Services program (MoIDX), has conveyed the validity of a Local Coverage Determination (LCD) reconsideration request for broader coverage for DetermaRx to include risk-stratification (in conjunction with TNM staging) to assess the risk of recurrence for the early-stage NSCLC patient to determine the best course of action for patient management.

"On the heels of the VA Contract announcement, we are very excited to share that we have received the confirmation of MoIDX's decision to recommend expanded coverage for DetermaRx pending the required public opinion period. Gaining this expansion as a risk of recurrence test allows physicians the choice of therapy for their high-risk patients, especially important given the interest in using immunotherapy earlier in the disease cycle," said Ron Andrews, Chief Executive Officer of Oncocyte. "We were also encouraged by the recommendation by CMS's advisory panel to move DetermaRx into a high-value category and await the posting of the final decision. DetermaRx continues to gain momentum as a powerful indicator of recurrence risk in early-stage NSCLC and to date has impacted the lives of well over 1100 lung cancer patients."

### **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.

Through its proprietary tests and pharmaceutical services business, the Company 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. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™ is a gene expression test that 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, DetermaCNI™, a blood-based monitoring test, DetermaMx™, a long-term recurrence monitoring test, and VitaGraft™, a blood-based solid organ transplantation monitoring test. 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 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 the expectation that CMS will post its preliminary decisions regarding DetermaRx in mid-September for public comments and issue a final determination in mid-November, and potential expanded LCD coverage for DetermaRx, 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 & Media Contact

Caroline Corner

ICR Westwicke

Tel: 415.202.5678

[caroline.corner@westwicke.com](mailto:caroline.corner@westwicke.com)



Source: Oncocyte Corporation

