Oncocyte Announces Final Medicare LCD from Palmetto for DetermaRx™

Apr 30, 2020

May lead to Medicare coverage for up to 70% of eligible early-stage lung cancer patients

IRVINE, Calif., April 30, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today announced that Palmetto, the Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (CMS), has issued a final local coverage decision for DetermaRx™. The test, which launched earlier this year via an early access program, is the first and only predictive test for the identification of patients with Stage I-IIA non-squamous NSCLC who are at high-risk for recurrence following surgery and are likely responsive to adjuvant chemotherapy.

“Today’s CMS decision is a significant milestone for Oncocyte. Not only can we now increase outreach to more patients and physicians around the country, but we believe several national and regional payers will follow this decision, giving additional patients insurance coverage for this important test,” said Ron Andrews, CEO of Oncocyte. “The DetermaRx test addresses a critical unmet need for the 30-50% of patients with early-stage lung cancer who have a recurrence despite having “curative” surgery. In a published clinical study, patients identified as high-risk by the DetermaRx test post-surgery and treated by chemotherapy had survival rate of 92% compared to high-risk untreated patients who had a survival rate of 49%.”

“Despite the impact of COVID-19, we have seen significant interest in this test just in the first quarter of launch, with twenty onboarded sites and more than 1500 attendees to physician education programs. Today’s CMS decision further supports the promise of DetermaRx, and we are looking forward to expanding our reach throughout the U.S. over the coming months.”

Following this decision, Oncocyte intends to intensify its efforts with private payers who have a history of following Medicare coverage decisions, with the goal of securing coverage for patients with private insurance.

Please visit CMS.gov to view the final local coverage decision memo.

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, with the goal of improving patient outcomes by accelerating and optimizing diagnosis and treatment. The Company recently launched DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. DetermaDx™, the company’s liquid biopsy test in development, utilizes a proprietary immune system interrogation approach to clarify if a patients’ lung nodules are benign, which

may enable them to avoid potentially risky invasive diagnostic procedures. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies. DetermaDx, DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

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 commercial launch of DetermaRx, development of DetermaDx and DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with 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 financial and operational results, risks inherent in the development and/or commercialization of potential 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 our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater than estimated allocations of resources to develop and commercialize technologies, or 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.

Investor Contact
Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Media Contact
Cait Williamson, Ph.D.
LifeSci Communications, LLC
646-751-4366
cait@lifescicomms.com

ONCOCYTE™

Source: OncoCyte Corporation

Powered by SITECORE