



Oncocyte Announces New Prospective Data Demonstrating That Treatment Informed by DetermaRx™ Significantly Improves Lung Cancer Patient Survival

Oct 14, 2020

Data to be Presented by Dr. Gavitt Woodard of Yale University at the IASLC 2020 North America Conference on Lung Cancer

Results and Clinical Utility to be Discussed During KOL Webinar on October 22nd at 11:00 am PT featuring Dr. Woodard and Dr. David Gandara of UC Davis

IRVINE, Calif., Oct. 14, 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 new prospective data on DetermaRx™ will be presented at the IASLC 2020 North America Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer. These data will be presented by Gavitt Woodard, M.D., Assistant Professor, Yale School of Medicine, and lead author on the study. DetermaRx is a treatment stratification test that identifies stage I-IIA non-small cell lung cancer (NSCLC) patients at high-risk of recurrence despite ostensibly curative surgery, who may benefit from the addition of chemotherapy. The test is reimbursed by Medicare and has seen rapid adoption in its first year of launch across seventy hospitals, including National Comprehensive Cancer Network (NCCN) and National Cancer Institute (NCI) cancer centers.

Presentation highlights from the prospective study of 250 consecutive stage I-IIA non-squamous NSCLC patients that received the DetermaRx test include:

- High-risk status as identified by the DetermaRx test was used to inform the use of adjuvant chemotherapy, and strikingly, 94% of patients who selected adjuvant chemotherapy were cancer-free after five years of follow-up. In contrast, one in three high-risk patients who elected to forego chemotherapy had a recurrence.
- No DetermaRx-identified low-risk patients were treated with chemotherapy, and only 5% of them reported a cancer recurrence, suggesting that this test may also inform the choice to avoid potentially unnecessary but toxic chemotherapy.
- These data expand and reinforce the strong survival benefit previously demonstrated in the first 100 patient study previously published.
- EGFR status was not prognostic when data was evaluated in a cohort of 150 patients
- DetermaRx identified high-risk patients who responded to adjuvant chemotherapy, independent of EGFR status
- Data presented at the annual ASCO meeting from the ADUARA trial, reported improved survival rates in surgically resected NSCLC patients with an EGFR mutation treated with the targeted therapy

osimertinib (Tagrisso®) These results inform the usage of the targeted therapy osimertinib in conjunction with chemotherapy, in EGFR positive patients.

“We are very pleased that the initial data showing this test’s impact on cancer recurrence was maintained in the 250-patient expanded data set. This result establishes DetermaRx as the post-surgical treatment standard for patients diagnosed with NSCLC,” said Dr. Edgardo S. Santos, M.D., Florida Precision Oncology, a Division of Genesis Care and an early adopter of the test. “The integration of testing for targeted therapy, including EGFR mutation status and chemotherapy selection by DetermaRx on the same sample, will enable oncologists to optimize and sequence treatment post-surgery. In my opinion, these two tests together close the few remaining gaps that we currently face in deciding adjuvant therapy for early-stage adenocarcinoma of the lung. With these results, I would feel confident initiating chemotherapy, followed by targeted therapy for the EGFR-positive, DetermaRx high-risk patients I see in my practice.”

Key takeaways include:

- Combining DetermaRx risk status with EGFR mutation status may help inform optimal treatment strategies for non-small cell lung cancer (NSCLC) patients who are EGFR-mutation-positive.
- DetermaRx may inform the usage of chemotherapy, in addition to osimertinib, in the approximately 33% of EGFR positive patients who DetermaRx also identified as high-risk for cancer recurrence.
- Given these data, Oncocyte will be offering EGFR mutation testing and DetermaRx on the same sample starting this quarter.

Padma Sundar, Senior Vice President, Commercial at Oncocyte, commented, “Coming off a very strong third quarter (during which we received final Medicare pricing within our expected range, and saw DetermaRx order volumes more than double from the second quarter), we are extremely excited about the release of the new prospective data. We believe these data expand the utility of DetermaRx for both chemotherapy and targeted therapy selection, ultimately facilitating continued rapid market adoption. As DetermaRx is the only validated test for guiding standard of care adjuvant chemotherapy post-surgery, we will continue to add other actionable markers to our testing as more therapy options become available for these patients. The addition of EGFR testing for osimertinib is an exciting first step in that direction.”

Results from the study will be discussed at a KOL webinar **on October 22nd at 11:00am PT** led by Gavitt Woodard, M.D., Assistant Professor, Yale School of Medicine, cardiothoracic surgeon and lead author on the study, and David Gandara, M.D., Professor of Medicine Emeritus at the University of California, Davis, and Director of Thoracic Oncology at the UC Davis Comprehensive Cancer Center (UCDCCC).

For more details on the webinar and to register, please click [here](#).

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’s proprietary tests and pharmaceutical services aim to 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 driving the growth of its revenue. Oncocyte 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. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint inhibitor and other immunotherapies. To strengthen the

Company's immune therapy diagnostic offering, Oncocyte recently announced plans to commercialize Therasure-CNI, a tumor naïve blood based test licensed from Chronix Bioscience, which has shown effectiveness at monitoring the efficacy of immune therapy. The Company also has a growing pharmaceutical services business to help pharmaceutical companies with biomarker development for new cancer treatments, some of which may be linked to Oncocyte's diagnostic tests.

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 DetermaIO, pharmaceutical services, 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

Source: Oncocyte Corporation

