Oncocyte Announces Completion of DetermaDx™ Clinical Validation Study

Jun 29, 2020

Prospective, blinded clinical validation study did not achieve pre-defined endpoint of improvement over routinely used clinical factors for managing patients with radiologically identified lung nodules

Company to now focus resources on accelerating DetermaRx™ and DetermaIO™, which are currently being commercialized for the clinical and biopharma markets, respectively

Conference call today, June 29, at 5:00p.m. EDT

IRVINE, Calif., June 29, 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 the completion of the Clinical Validation study of DetermaDx™, the Company's liquid biopsy test intended to clarify whether a lung nodule is suspicious or likely benign. Findings from the Clinical Validation study demonstrated that the performance of DetermaDx did not meet the predetermined endpoints for the study.

"DetermaDx represents Oncocyte's legacy work on the first step of the cancer care continuum – diagnosis. Appropriate management of incidentally identified lung nodules is critical, as early diagnosis of lung cancer has a significant impact on patient survival," said Ron Andrews, Chief Executive Officer of Oncocyte. "We had one main criteria for the launch of our test in designing our clinical validation study: statistically significant improvement over and above the clinical factors being utilized by physicians today to help with the diagnosis of intermediate risk nodules, particularly in the 0.8-2.2cm nodule size range. Unfortunately, DetermaDx did not achieve that endpoint in Clinical Validation."

Mr. Andrews continued, "Based on the results of the Clinical Validation study, we have made the decision to cease further investment in DetermaDx and focus our efforts on maximizing the significant opportunities that we see for our two more advanced commercial tests. We have a balanced portfolio of tests in market launch phases and are enthusiastic about the Company's progress over the last year and our future prospects."

The Company made two important acquisitions over the last year and has commercialized two tests in 2020. DetermaRx, intended for treatment selection in early stage lung cancer management, is launched for clinical use. It is covered by Medicare, has been reimbursed by several commercial payers and is gaining traction in community-based health systems despite the challenges in the macroenvironment relating to the COVID-19 pandemic. This test has a global opportunity of more than 350,000 patients annually and a worldwide market size of over $500M.

The second test is DetermaIO for immunotherapy response prediction, with studies completed in non-small cell lung cancer and triple negative breast cancer by researchers at the West Clinic and MD

Anderson Cancer Center, respectively, with results presented at SITC 2019 and the ASCO 2020 annual meetings. This test is currently available for biopharma diagnostic development and research use only and has significant potential as a companion test to select patients for clinical trials and, ultimately, as a full companion diagnostic for clinical use of immunotherapies in patient management. With close to 800,000 patients eligible to receive immunotherapies in the U.S. alone, and no robust test available that provides a clear understanding of which patients are most likely to have a sustained response to these costly therapeutics, we believe this may represent a significant opportunity for DetermaIO.

Concluding, Mr. Andrews said, "The strategic vision of being a one lab resource for physicians managing lung cancer patients remains intact despite today's news. We look forward to continuing our current organizational velocity as we now focus on gaining commercial traction with our recently launched tests."

Conference Call

Oncocyte management will host a conference call today, June 29, 2020, at 5:00 p.m. EDT / 2:00 p.m. PDT to discuss the results. To access the call, please use the information below.

The dial-in number in the U.S./Canada is 877-407-9716; for international participants, the number is 201-493-6779. For all callers, please refer to Conference ID 13706319. To access the live webcast, go to the investor relations section on the Company's website, or by clicking here:
http://public.viavid.com/index.php?id=140543

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. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies.

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.

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