



Oncocyte Presents New Data on Its DetermalO™ Test at Association for Molecular Pathology (AMP) 2020 Conference

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Data demonstrate that DetermalO™ can be run successfully using limited tissue from small biopsy specimens, overcoming the significant challenges associated with tissue availability for molecular testing

Low tissue requirement may help to identify more patients for immunotherapy treatment

IRVINE, Calif., Nov. 18, 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 presentation of data on its DetermalO™ test at the Association for Molecular Pathology (AMP) 2020 Virtual Conference being held virtually November 16-20. DetermalO is a CLIA validated test currently available for research use in clinical trials. The test uses real-time PCR to measure expression of 27 genes and a proprietary immune-oncology (IO) algorithm with demonstrated predictive capabilities for patient response to immune checkpoint inhibitor (ICI) therapies in non-small cell lung cancer (NSCLC) and triple-negative breast cancer (TNBC). The biology behind the test, which assesses the entire tumor microenvironment, may identify resistance mechanisms that may be overcome by second generation therapies.

These new data being presented at AMP demonstrate that the test is reproducible at tissue inputs compatible with small tissue samples, thus potentially increasing the number of patients who would qualify for testing. As little as 2mm² of tissue, or a single slide, was required to generate reproducible results in the study. This tissue requirement is as much as ten-fold lower than required for some marketed NGS gene panel tests. For example, PD-L1 testing requires 3-5 slides while tumor mutational burden (TMB) requires as many as ten slides for testing, often times exhausting the tumor tissue available. In lung cancer, it is estimated that 15-30% of samples from biopsies have insufficient tissue for standard molecular tests. The Company believes that these data, together with an anticipated turnaround time of three to five business days for test results, could position DetermalO as a convenient and practical choice when the test becomes available for use in routine clinical testing.

“Managing late stage cancer patients and guiding therapy decisions can be challenging due to limited tissue samples and the large amount of tissue required to run NGS testing and other molecular diagnostics,” said Doug Ross, M.D., Ph.D., Chief Medical Officer of Oncocyte. “In lung cancer, we are often limited to a fine needle aspirate, which leads to over 25% of patients not able to receive targeted panel or TMB testing. These data presented at AMP add to the growing body of evidence on the checkpoint inhibitor predictive capability of DetermalO and importantly, as a PCR-based test, may allow its rapid adoption regardless of the quantity of tissue available. The minimal tissue requirements for successful test performance reported at AMP mean that a large number of patients could potentially qualify for testing with DetermalO, overcoming challenges sometimes seen with targeted testing. In addition,

preserving precious tissue samples may allow pathologists to also perform other important tests which could aid in a more thorough initial diagnosis and therapy decisions. We look forward to moving this work forward as we increase the adoption of DetermaIO in the research setting in pharma and academia, with an ultimate goal of making the test available in the clinical setting to provide comprehensive IO solutions to patients and physicians.”

Details on Oncocyte’s poster presentation:

Title: *Tissue Requirements of a Novel 27-Gene Immuno-Oncology Algorithm Measuring Tumor Microenvironment to Predict Response to Immunotherapies*

Authors: Tyler J Nielsen, Frank B McMahon, Jeremy Spille, David R Hout, Kim Dickinson, Brock L Schweitzer

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 company 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 across four growth engines. 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 also has launched, as a Research Use tool for Biopharma clinical trials, DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint inhibitor immunotherapies. The Company’s pharmaceutical company services help pharmaceutical companies to develop new cancer treatments, many of which may be linked to Oncocyte’s diagnostic tests. The final growth engine is the recently licensed CNI test for blood based therapy monitoring in patients receiving immune therapy, which the company plans to launch as a Research Use tool for Biopharma clinical trials in 2021.

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, 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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Source: Oncocyte Corporation

