Oncocyte Announces the Launch of CLIA-validated DetermaIO™, a Novel Gene Expression-Based Immune Therapy Response Predictor, for Research Use by Biopharmaceutical Companies and Researchers

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Company completes CLIA Validation of DetermaIO™, previously the Insight Genetics IM Score Test, establishing the test as a reliable and robust assay for identifying patients likely to respond to checkpoint inhibitor therapy

Data presented at the SITC conference in 2019 suggested that DetermaIO™ outperforms PD-L1 testing and Tumor Mutational Burden (TMB) in predicting both responders and non-responders to checkpoint inhibitors

IRVINE, Calif., March 19, 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 it had completed CLIA Validation for DetermaIO™, previously the Insight Genetics IM Score Test. The company has also officially launched DetermaIO™, making it available for research use within the biopharmaceutical and academic communities. With its ability to predict responders and non-responders to checkpoint inhibitor therapy, DetermaIO™ has the potential to be used to stratify patients in the over 3,000 PD-1/PD-L1 ongoing clinical trials that are collectively expected to recruit over 500,000 patients, representing a large pharma services opportunity.

DetermaIO™, a key component of the Insight Genetics acquisition, is a gene expression profile test that evaluates the immune microenvironment in biopsies from cancer patients to identify individuals more or less likely to respond to anti-PD-1/PD-L1 immunotherapy. The DetermaIO™ test differentiates itself from the current leading immunotherapy diagnostic tests by having the capability to determine if the immune microenvironment is active (“hot”) or quiescent (“cold”). Data presented at SITC (Society for Immunotherapy of Cancer) in 2019, suggested DetermaIO™ may be superior to two currently marketed predictive companion diagnostic tests for immunotherapy selection, PD-L1 IHC staining (22c3, Dako) and tumor mutational burden (TMB). DetermaIO™ is performed in Oncocyte’s lab in Nashville TN, an ISO:9001, CLIA and College of American Pathologists (CAP)- accredited lab which incorporates 21 CFR 820 practices by adherence to design control protocols. This quality system ensures test results exceed pharmaceutical industry standards for clinical laboratory testing. The lab has been qualified by multiple top-20 diagnostic and pharmaceutical firms for clinical sample testing.

“Identifying which patients will benefit most from immunotherapy remains an outstanding question for oncologists and pharmaceutical researchers,” said Gregory Vidal, M.D., Ph.D., the principal investigator of the study presented at SITC and Assistant Professor of Hematology/Oncology at the University of Tennessee Health Science Center. “The data presented at SITC was incredibly promising, and the

community is looking forward to seeing the impact the test can have on a broader patient population. I believe it has the potential to streamline the development of new therapies and improve patient outcomes."

Ron Andrews, Chief Executive Officer of Oncocyte added, "We are thrilled to have reached such an impactful set of milestones for DetermaIO™ so quickly, which is indicative of the incredible team we inherited upon completion of our acquisition of Insight Genetics in January. The commercial availability of our IO test for pharma and academic research further establishes Oncocyte as a leader when it comes to both diagnosis and treatment planning for lung cancer. The promising solid performance characteristics of DetermaIO will allow us to simultaneously pursue a CE Mark Kit strategy in Europe where we can access the installed base of the leading PCR platform manufacturers. This type of test democratization is essential for pharma to ensure patients around the world have access to the testing that will qualify them for the most appropriate course of a particular therapy. I continue to be enthusiastic about our organizational velocity as we advance multiple product efforts simultaneously."

Doug Ross, MD, Ph.D., Chief Medical Officer of Oncocyte, concluded, "With the completion of our successful CLIA validation, pharma partners interested in using DetermaIO™ for clinical studies can be confident in the results obtained and the quality of the CLIA and CAP-accredited laboratory in which the test is being performed. These CLIA Validation data demonstrate DetermaIO™ to be highly reproducible with minimal tissue input requirements and resistance to inhibitors common in FFPE tissue. We intend to present additional details at upcoming medical meetings in the summer and fall and anticipate engaging with new partners in the biopharma and research communities. With our East Coast CLIA laboratory officially up and running in Nashville, we look forward to joining forces with pharma companies and academic research centers to better understand patient response to immunotherapy."

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.

Oncocyte Forward Looking Statements

Oncocyte cautions you that this press release contains forward-looking statements concerning, but not limited to, the commercial launch of DetermaIO for research use. 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 development of DetermaDx and the ongoing Clinical Validation study, the impact of the commercial launch of DetermaRx, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from the acquisition of Insight Genetics, 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, 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 the anticipated benefits of the acquisition, unexpected expenditures or assumed liabilities that may be incurred as a result of the acquisition, unanticipated difficulties in conforming business practices, including accounting policies, procedures and internal controls, greater than estimated allocations of Oncocyte resources to develop and commercialize Insight Genetics 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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