Oncocyte Announces the Clinical Launch of DetermaIO Immunotherapy Response Prediction Test

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DetermaIO is the first and only immunotherapy clinical test that comprehensively assesses the tumor microenvironment

In clinical studies to date across multiple tissue types, DetermaIO has consistently proven to be more precise at identifying patients who are immunotherapy responders including those who may have been missed by PDL-1 IHC and other biomarkers

IRVINE, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer, today announced the clinical launch of its DetermaIO™ test. DetermaIO is a proprietary gene expression test that assesses the tumor immune microenvironment (TIME) to predict response to immunotherapy. In multiple clinical studies evaluating hundreds of patients across multiple tumor types, including lung, breast, bladder and renal cancers, the test has demonstrated the ability to predict response to immune checkpoint inhibitors (ICI) which has the potential to help inform the optimal use of immunotherapy treatment for more than one million eligible patients annually in the United States alone.

“For my patients with lung cancer, there are myriad treatment options including mono immunotherapy, combination immunotherapy with chemotherapy, and even a combination of two immunotherapies, each with their benefits and risks in terms of toxicity and side effects,” said Dr. Nagdala Abdel-Karim, Director of the Thoracic Oncology Multidisciplinary Clinic and Medical Director of the Georgia Cancer Centers Clinical Trials Program. “Therefore, selecting the right immunotherapy regimen for the patient is a very complex decision. We use PD-L1 and occasionally tumor mutational burden (TMB), but neither biomarker is completely accurate or takes into account both the tumor and its microenvironment, which is important as both determine response to immunotherapy. I am impressed with the DetermaIO data, especially the superior progression free survival relative to legacy biomarkers and feel confident it will enable us to better navigate the immunotherapy decision.”

In studies in multiple solid tumors presented at oncology congresses around the world, including at the European Society of Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO), and American Association of Cancer Research (AACR), and in a peer-reviewed publication with authors from MD Anderson and Yale, DetermaIO has demonstrated superior utility in identifying patients who may respond to immunotherapy compared to alternative biomarkers in development. DetermaIO has also demonstrated superior utility in identifying patients who are unlikely to benefit from these immune therapies which can cause serious, long-lasting side effects. In a study presented at the recent ESMO congress, triple negative breast cancer patients randomized to receive either neoadjuvant chemotherapy

alone or chemotherapy combined with an immune checkpoint inhibitor, DetermaIO positive patients had a 20% higher pathologic complete response only when an ICI was added to standard of care chemotherapy (71% response compared to 51%), while those patients who were DetermaIO negative showed no additional benefit from the addition of immunotherapy to a standard of care regimen. This study confirmed findings in a previously published study where ICI given in combination with standard neoadjuvant chemotherapy showed far superior benefit in DetermaIO positive patients compared to DetermaIO negative.

Padma Sundar, Chief Commercial Officer of Oncocyte, said, "Given the data presented to date, there is strong interest among physicians to access this test and incorporate it into their practice to aid in the complex decision making for immunotherapy treatment. We are launching the test initially as part of an early access program to optimize sample processing and logistics, targeting sites that have successfully partnered with Oncocyte on prior tests. Recruitment for the early access program is ahead of schedule and clinical samples are expected to begin coming in before the end of the year. Demonstrating test adoption is an important step towards pursuing Medicare reimbursement, along with peer reviewed publications which are in process, and we remain committed to deliver our reimbursement dossier in the first half of 2022."

Ms. Sundar continued, "The next step in our menu roll out is to combine DetermaIO with DetermaTx, a DNA/RNA based comprehensive genomic profiling test, which already has established Medicare reimbursement rates. With both tests performed on a single sample, we will deliver the most complete and differentiated biomarker information needed to make both immunotherapy and targeted therapy decisions to treating physicians, while conserving precious sample and minimizing turnaround time. This, combined with DetermaCNI, our blood-only test for treatment resistance monitoring currently in clinical trials, builds on our 'one-lab' offering, and will differentiate us with oncologists. Our one lab and sample sparing approach strengthens our position as an emerging leader in precision oncology testing."

The launch of DetermaIO is built on the growing body of evidence on the clinical applications of the test, suggesting a potential pan-cancer and pan-immunotherapy utility in both primary and metastatic settings. In combination with the Company's robust pipeline of diagnostic and monitoring tools, as well as its recently-launched real world cancer registry in early stage NSCLC for DetermaRx, this launch underscores Oncocyte's commitment to driving rigorous science in order to empower surgeons, physicians, and their patients to better manage the oncology patient journey.

About DetermaIO™

DetermaIO™ is a 27-target multivariate gene expression test performed on FFPE biopsy specimens that measures the presence of subtypes of infiltrating inflammatory cells, and the presence or absence of a differentiated stromal microenvironment. DetermaIO's proprietary algorithm combines mRNA gene expression data to interpret the physiology of both the tumor and its surrounding micro-environment in order to predict the response to immuno-oncology therapies. For more information, visit www.oncocyte.com/products/determa-io.

About Oncocyte

Oncocyte is a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research-use only tool, assesses the tumor microenvironment to predict response to immunotherapies.

The Company's pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, blood-based monitoring test DetermaCNI™, and long-term recurrence monitoring test DetermaMx™. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx™, DetermaIO™, DetermaTx™, DetermaCNI™ and DetermaMx™ 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 DetermaIO and its potential to help inform the optimal use of immunotherapy treatment for more than one million eligible patients annually in the United States alone; the belief that DetermaIO will enable treating physicians to better navigate the immunotherapy decision; the Company's plans to combine DetermaIO with DetermaTx; the expectation that, by performing both DetermaIO and DetermaTX on a single sample, the Company will deliver the most complete and differentiated biomarker information needed to make both immunotherapy and targeted therapy decisions to treating physicians, while conserving precious sample and minimizing turnaround time; and 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 Oncocyte or its subsidiaries' financial and operational results, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, and the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential 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 (SEC) 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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