# Oncocyte Announces Peer-Reviewed Publication of Data Assessing Use of DetermaIO™ to Identify Patients Likely to Benefit from Immunotherapy Across Multiple Tumor Types

Mar 16, 2021

*Novel immuno-oncologyalgorithmmay offer independent and incremental predictive value over current standard biomarkers in the clinic*

*Data suggest that measuring the tumor microenvironment (TME) as a whole may help optimize immunotherapy use in the clinical setting*

*Authors concluded that the immuno-oncology algorithm is capable of analyzing data from multiple platforms that have a wide global installed base, including PCR and NGS, and from gene expression data already available from pharma clinical trials without the need for any tissue*

IRVINE, Calif., March 16, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, announced findings from a study using the DetermaIO™ immuno-oncology algorithm to assess patients likely to benefit from immunotherapy across multiple cancer types. The study, "A novel immuno-oncology algorithm measuring tumor microenvironment to predict response to immunotherapies," was recently published in a peer-reviewed article in *Heliyon*, and is accessible at this link.

Immunotherapies using immune checkpoint inhibitors (ICIs) are widely considered standard of care in the treatment of lung cancer, breast cancer, and other solid tumor types. However, while ICI therapies have been shown to improve clinical outcomes for certain patients, data indicate that only 20-40% of the approximately 750,000 patients in the US eligible annually for ICI respond to those therapies. In addition, ICI therapies have been shown to cause adverse immune-related events that can be life-threatening for some patients. Standard of care PD-L1 testing incorrectly identifies many patients as potential responders to immune checkpoint inhibitors, and misses certain other patients who may respond. Therefore, there appears to be an unmet need for a better predictive biomarker that can identify patients that will likely benefit from ICI therapy.

The study's researchers hypothesized that measuring the activity of the tumor microenvironment (TME) may be useful in patient selection for ICI therapy, and developed a novel algorithm that can be applied to gene expression data from a small set of most relevant genes, potentially making the assay practical and cost effective for clinical use.

"Unlike previously described biomarker models, the novel immuno-oncology algorithm behind DetermaIO measures the immunological state of the TME as a means to capture the interplay of the

patient's immune system and tumor immune evasion. Our hypothesis was that because the test measures the TME as a whole, the predefined threshold may have utility across several tumor types," said Tyler Nielsen, lead author of the study and Senior Scientist at Oncocyte. "We established a threshold for positivity in triple negative breast cancer specimens, and as this study shows we were able to apply it to a non-small cell lung cancer cohort. We believe that this algorithm may give DetermaIO independent and incremental predictive value over the current gold standard biomarkers in the clinic."

"As demonstrated by the translation of this signature from triple negative breast cancer to non-small cell lung cancer, the classifier appears to be applicable across multiple solid tumor types," stated Doug Ross, M.D., Ph.D., and Chief Science Officer of Oncocyte. "We believe that DetermaIO may also be highly appealing for use in both pharma driven clinical studies and well as in the clinic. The test is currently performed centrally in our labs using our CLIA certified RT-PCR assay starting with very little tissue from biopsy specimens. The test utilizes gene expression data from any type of biopsy or surgical specimen, which can be generated on most NGS or PCR platforms, making it suitable for worldwide distribution. It can also be assessed on gene expression data that has often already been generated by pharmaceutical companies in their clinical trials, avoiding the need for tissue. This has been a very attractive value proposition to our pharmaceutical clients because we can help generate data quickly to demonstrate the utility of DetermaIO for their specific drug in development."

Dr. Ross continued, "As DetermaIO works primarily by assessing the inflammatory cells and the cancer wound response, we are encouraged that DetermaIO may be relevant across multiple tumor types and useful in clinical studies being conducted by pharma companies, providing a means to distinguish patients likely to benefit from treatment with ICIs."

Other key highlights of the study include:

- The study examined ten patients with two samples each—one from the tumor itself and one from the surrounding TME and used the algorithm to generate DetermaIO scores for each pair of matched samples. The agreement between the two samples across the ten patients was 92%. The ability to get concordant results from two different sampling sites may imply that DetermaIO will have greater flexibility in tissue requirements than similar tests.

- The DetermaIO score generated by the algorithm was applied to samples from lung cancer patients treated with ICI and was able to distinguish between tumors that responded to ICI and tumors that did not respond.

- The endpoint used in the study was sustained response, measured by no progression within six months. Using the six month response endpoint reflects DetermaIO's ability to identify a durable response.

**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, through its proprietary tests and pharmaceutical services business, aims to help 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 also driving revenue growth for the Company. Oncocyte recently launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™, a test to assess

mutational status of a tumor to help identify the appropriate targeted therapy, in the second half of 2021. The Company previously announced its planned acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor test, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation. Therasure is a trademark of Chronix Biomedical Inc.

**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 potential clinical use of DetermaIO across multiple tumor types, 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 or any distributor's 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 or any distributor's supply chain, 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 we commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality 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:
Terri Clevenger
Westwicke/ICR
203-856-4326
Terri.clevenger@westwicke.com

ONCOCYTE

Source: Oncocyte Corporation

Powered by SITECORE