



## Oncocyte Presents DetermalO™ Data at ASCO 2022 Supporting the Test's Potential to Expand the Clinical Use of Immunotherapy

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*DetermalO identifies responders to immunotherapy among the 95% of patients with colon cancer currently ineligible for treatment based on existing biomarker, addressing a significant unmet need*

*DetermalO test now validated by 10 studies in six tumor types across four leading immune checkpoint inhibitors*

IRVINE, Calif., May 26, 2022 (GLOBE NEWSWIRE) -- [Oncocyte Corporation](#) (Nasdaq: OCX), a precision diagnostics company with the mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey, announced today new data from ongoing clinical research evaluating the utility of DetermalO™, the Company's proprietary test designed to determine the likelihood of benefit of immune checkpoint inhibitors (ICIs), at the upcoming American Society of Clinical Oncology Annual Meeting (ASCO), taking place June 3-7, 2022 virtually and in-person in Chicago.

DetermalO was launched via an Early Access Program in Q4 of 2021 and is the first and only commercial test to assess multiple components of the tumor immune microenvironment (TIME), giving insight into the biology of the tumor that allows for physicians and their patients to make informed decisions about their treatment journey. The three posters to be presented by Oncocyte add to the growing body of evidence showing that the test identifies patients who respond to ICIs – including Keytruda®, Opdivo®, Tecentriq® and Imfinzi® – in lung, bladder, kidney, triple-negative breast, and now colon and gastric cancers, suggesting a pan-cancer utility for the test in both primary and metastatic settings.

- **An immune-related gene expression profile to predict the efficacy of adding atezolizumab to first-line FOLFOXIRI plus bevacizumab in metastatic colorectal cancer: A translational analysis of the phase II randomized AtezoTRIBE study.** [Abstract #3581], recipient of Marcia Mataldi Endowed Merit Award from ASCO's Conquer Cancer Foundation, profiles the AtezoTRIBE study and highlights data supporting that DetermalO's deep characterization of the TIME helps identify patients with colon cancer likely to benefit from immunotherapy. AtezoTRIBE previously demonstrated that the addition of Tecentriq (atezolizumab), an ICI developed and marketed by Roche, benefited some patients with metastatic colorectal cancer (mCRC), but that the current biomarker, which identifies only about 5% of those with colon cancer, misses a significant fraction of responders. For the other 95% of patients, those with proficient mismatch repair (pMMR) tumors, identifying a subgroup able to achieve benefit from ICIs is crucial. Researchers assessed the role of DetermalO to predict clinical benefit from the addition of an ICI to first-line chemotherapy in patients with mCRC, finding that 27% of patients in this study were DetermalO positive. Identification of these patients had a significant association with progression free survival (PFS) regardless of whether they were in the pMMR group

or not.

“These results are exciting as they show DetermaIO may be helpful to predict treatment benefit for patients in metastatic colorectal cancer, including the patients with pMMR tumors. Furthermore, they potentially show the value of tests that reflect the broader tumor immune microenvironment in identifying mCRC patients who are more likely to benefit from ICI-based therapies,” said Chiara Cremolini, President of GONO Foundation and Principal Investigator of the AtezoTRIBE trial.

- **Association of 27-gene IO score with outcome in a phase Ib trial of pembrolizumab (pembro) plus chemotherapy (CT) in metastatic triple-negative breast cancer (mTNBC) [Abstract #1082]** builds on previously released data showing DetermaIO predicts benefit of treatment with Tecentriq over neoadjuvant chemotherapy alone in non-metastatic triple negative breast cancer (TNBC). The data confirms that DetermaIO also has the ability to predict benefit of treatment with Keytruda (pembrolizumab) in mTNBC. Currently Keytruda is approved in this setting for the 38% of patients who are PD-L1 positive. The study evaluated clinical response to Keytruda plus chemotherapy in mTNBC patients, showing DetermaIO was predictive of response regardless of PD-L1 status. In addition, the test could identify PD-L1 negative tumors that respond to Keytruda plus chemotherapy, addressing an unmet need for the 62% of patients who are currently ineligible for treatment with an ICI in this indication. These new data demonstrate DetermaIO’s utility in TNBC with two ICIs: Tecentriq and Keytruda, the most commonly-prescribed ICI’s for this indication.
- **The 27-gene IO score is associated with molecular features and response to immune checkpoint inhibitors (ICI) in patients with gastric cancer [Abstract #4058]** suggests that DetermaIO may be a more comprehensive biomarker for clinical decision making in gastric cancer due to its unique properties of characterizing the TIME. Data was obtained from three independent cohorts including The Cancer Genome Atlas Program (TCGA), The Asian Cancer Research Group (ACRG), and a clinical cohort with ICI response data. Importantly, in the clinical cohort of 59 patients, DetermaIO was statistically significantly associated with ICI response. The TCGA and ACRG cohorts showed that DetermaIO was associated with a number of biomarkers used to identify patients who are most likely to benefit from ICI therapies, potentially implying that a single DetermaIO test could replace the several tests that are currently run concurrently on each patient sample. With gastric cancer being the third-leading cause of cancer-related death worldwide, DetermaIO may fill the unmet need for a biomarker that can better predict response to ICI therapies.

“We are thrilled to present this group of data at ASCO this year, which build on the seven previous studies that support DetermaIO,” said Rob Seitz, Head of Immune Oncology at Oncocyte. “The studies over the past two years have established a solid foundation for DetermaIO’s use as a predictive test in four major tumor types. The exciting data from the colon trial opens up a fifth and extremely important indication given there is a very large patient population in CRC that, today, has no option for life saving ICI therapies. We are on schedule to deliver our CMS dossier in the second half of 2022 and look forward to bringing this important test to a full market launch.”

The ASCO 2022 [virtual program](#) and [abstracts](#) are currently available online at the ASCO 2022 website.

In addition, Oncocyte is supporting a Continuing Medical Education Event (CME) by way of an unrestricted educational grant on Sunday, June 5, 2022, at 6:30PM CDT. The program, entitled Convergence of Molecular Diagnostics and Tumor Microenvironment to Improve Personalized Medicine in Breast, Lung, and Colorectal Cancers, will be chaired by David Gandara, MD (UC Davis Comprehensive Cancer Center). Charu Aggarwal, MD, MPH (Abramson Cancer Center, University of Pennsylvania), Heinz-Josef Lenz, MD

(USC Norris Comprehensive Cancer Center), and Priyanka Sharma, MD (University of Kansas Medical Center) will comprise the faculty.

This 90-minute session, held adjunct to the 2022 ASCO Annual Meeting, will offer updates on the latest advances in molecular diagnostic tools and biomarkers to help guide personalized therapies and predict which patients will have the best outcomes. Novel diagnostic tools have the potential to enhance treatment decision-making, optimize immunotherapy selection, and ultimately improve patient care.

*Disclaimer: Not an official event of the 2022 ASCO Annual Meeting. Not sponsored, endorsed, or accredited by ASCO®, CancerLinQ®, or Conquer Cancer® the ASCO Foundation.*

## **About Oncocyte**

Oncocyte is a precision diagnostics company with a mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey.

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 post-diagnosis treatment. 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 test DetermaCNI™, which can monitor cancer patients for recurrence of disease, long-term recurrence monitoring test DetermaMx™, and blood-based solid organ transplantation monitoring test TheraSure™. 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™, DetermaMx™ and TheraSure™ are trademarks of Oncocyte Corporation.

## **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, among other things, the anticipated delivery of a CMS dossier in the second half of 2022, the expected full market launch of DetermaIO, 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, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, 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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