



## Spotlight Poster Presentation at San Antonio Breast Cancer Symposium SABCS 2021 Shows Oncocyte's DetermalO™ Clinical Test Predicts Response to Immunotherapy in Triple Negative Breast Cancer

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*Data supports the use of DetermalO as a pan-cancer diagnostic tool, now addressing an unmet need for patients with triple negative breast cancer, the most aggressive type of breast cancer*

*DetermalO shown to work across multiple platforms, including PCR and NGS, with the potential to be used for pan-cancer diagnostic testing worldwide*

*Oncocyte supported a Continuing Medical Education event on Immunotherapy Biomarkers at SABCS, hosting key opinion leaders from the United States and Europe*

IRVINE, Calif., Dec. 09, 2021 (GLOBE NEWSWIRE) -- [Oncocyte Corporation](#) (Nasdaq: OCX), a precision diagnostics 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 results showing the ability of the Company's DetermalO™ test, a commercially-available precision diagnostic designed to determine the likelihood of response to immunotherapies (IO), at the 2021 San Antonio Breast Cancer Symposium (SABCS 2021).

The spotlight poster, titled "**Predictive value of RT-qPCR 27-gene IO score and comparison with RNA-Seq IO score in the NeoTRIPaPDL1 trial,**" confirms data presented at ESMO in a prospectively defined, randomized clinical study, that the launched, CLIA LDT PCR version of DetermalO predicts response to neoadjuvant atezolizumab therapy in triple negative breast cancer (TNBC). Moreover, the IO score maintained its predictive value in PD-L1 negative patients treated with chemotherapy plus immunotherapy, highlighting the failure of current biomarkers to identify all candidates for the immune therapy treatment.

The data also details the high-level concordance (92%) between the commercial test compared to the previously-reported NGS RUO (RNA-sequencing/RNA-Seq) version of the same test. The comparison demonstrated the strikingly high reproducibility of the test regardless of where a sample is analyzed or what platform is used. This underscores the quality of the assay as a disease classifier and therefore helps explain its unique ability to predict response to immune therapy using the same algorithm and threshold in different tumor types.

DetermalO has previously been shown to identify patients who respond to immunotherapy in lung, bladder, kidney cancers, as well as appropriately classify the immune system in other solid tumor types, suggesting a pan-cancer utility in both primary and metastatic settings. It has outperformed PD-L1

testing, and identified responders missed by this biomarker. The data presented at SABCS is expected to remove a barrier to wider adoption and can help address an unmet need for patients with TNBC.

“For the first time in a blinded study performed by our partners in Milan, we have shown that DetermaIO will deliver the same results measured on data from NGS as our CLIA certified assay. RNAseq data is available from many completed clinical trials and these results will allow partners to effectively preserve precious tissue samples and / or run studies on data from samples that are no longer available,” said Rob Seitz, Head of Immune Oncology at Oncocyte. “This effectively bridges the DetermaIO data between NGS gene expression and the clinically available RT-qPCR test, which we expect will dramatically accelerate our ability to provide these essential insights to other tumor types and instill confidence that the results translate in order to support clinical use. In addition, while using PCR technology in the clinical setting may have an advantage over the more expensive and slower NGS methods that require more tissue, this concordance supports potential deployment of DetermaIO as a kit on the huge installed base of PCR platforms enabling access of the test and associated therapeutics to labs on a global scale.”

“The identification of biomarkers for optimization of immunotherapy is an unmet clinical need for breast cancer patients,” said Doug Ross, MD, PhD, Chief Science Officer of Oncocyte. “Selecting the right treatment for the patient upfront can make a big difference to quality of life by avoiding long-term autoimmune side effects and prolonging survival. This is why physicians value tests like DetermaIO to help inform decisions. Many patients with triple negative breast cancer will respond incredibly well to a standard of care chemotherapy, especially in the early-stage setting, while others can benefit from immunotherapy. In the NeoTRIP trial, DetermaIO demonstrated the ability to identify and distinguish these patients. We appreciate the presentation of these data at SABCS 2021 by our collaborators from the Fondazione Michelangelo who share our commitment to improving patient outcomes by providing rigorous, validated tests targeted to informing the management of patients at key decision points along the patient journey.”

At SABCS, Oncocyte also supported a Continuing Medical Education event on immunotherapy biomarkers, hosting key opinion leaders from the United States and Europe.

## **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™, DetermaMx™ and TheraSure™ 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, among other things, the potential to use DetermaIO for pan-cancer diagnostic testing worldwide, the expectation of wider adoption of DetermaIO and its ability to address an unmet need for patients with TNBC, the potential deployment of DetermaIO as a kit on the huge installed base of PCR platforms enabling access of the test and associated therapeutics to labs on a global scale, the expectation that our ability to provide essential insights to other tumor types will dramatically accelerate and instill confidence that the results translate in order to support clinical use, 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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