



Oncocyte Publishes Study Demonstrating Predictive Potential for DetermalO® Test in Triple Negative Breast Cancer

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Data show that DetermalO demonstrates superior accuracy compared to standard of care PD-L1 IHC for predicting a patient's response to immunotherapy

IRVINE, Calif., Sept. 30, 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 publication of peer-reviewed data showing the strong predictive ability of its 27-gene DetermalO™ test in predicting immunotherapy (IO) responses in high-risk early-stage triple negative breast cancer (TNBC). The article titled [“A Novel Immunomodulatory 27-Gene Signature to Predict Response to Neoadjuvant Immunochemotherapy for Primary Triple-Negative Breast Cancer”](#), was published in the journal *Cancers*.

Oncocyte's DetermalO is a precision diagnostic test used to determine the likelihood of a patient response to immunotherapy and is the only multivariate diagnostic test that has shown prediction of immune therapy response in multiple tumor types using the same test and threshold. The study published in the journal *Cancers* suggests that the test can inform treatment decisions as early as the neoadjuvant setting, where treatment with immunotherapies can shrink a tumor before surgery and potentially allow for improved post-surgery outcomes. Existing studies support DetermalO's utility in advanced lung, renal and bladder cancers.

This newly published validation study of DetermalO in TNBC, was a partnership with researchers from MD Anderson, Yale University, and Baylor University who collected baseline core needle biopsy samples from 55 patients with stage I-III primary TNBC who were enrolled in a neoadjuvant clinical trial assessing the effectiveness of IMFINZI® (durvalumab) combined with chemotherapy. For this specific analysis, the researchers extracted RNA from the biopsy specimens and evaluated them with Oncocyte's DetermalO test, with the goal of predicting a patient's pathologic complete response (pCR) when treated with neoadjuvant use of IO, IMFINZI®, in combination with chemotherapy.

The researchers found that DetermalO was significantly associated with response to treatment and superior to PD-L1 immunohistochemistry (IHC), the standard biomarker employed for informing use of immune checkpoint inhibitors. Interestingly, the researchers explored a combination of PD-L1 IHC and DetermalO and found potential utility in the combined use of these markers to most accurately identify responders. These results are meaningful as they address an unmet need for a biomarker that can identify patients with TNBC who are most likely to respond to immunotherapy, and conversely those who

are less likely to benefit and may choose to avoid the significant side effects that can affect long term survivors.

“DetermalO continues to prove its potential to be a precision diagnostic that identifies both responders and non-responders to IO treatment regardless of which checkpoint inhibitor drug is chosen. This publication in *Cancers* shows that DetermalO may inform the use of the checkpoint inhibitor, IMFINZI, in neoadjuvant treatment in early stage Triple Negative Breast Cancer, a finding that was confirmed in the recent NeoTrip randomized trial using Tecentriq, data that was presented recently as a podium presentation at the ESMO Annual Meeting. We now have two independent studies in TNBC supporting the ability DetermalO to predict response to neoadjuvant checkpoint therapy in TNBC,” said Rob Seitz, Head of Immune Oncology at Oncocyte. “We look forward to reporting on our continued work to expand DetermalO’s utility in multiple cancer types to ensure more patients can benefit from the clarity that precision oncology diagnostics can provide.”

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. DetermalO™, 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™, DetermalO™, 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 the Company’s continued work to expand its DetermalO’s utility in multiple cancer types 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 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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