



Oncocyte To Present New Data at 2021 American Association for Cancer Research (AACR) Annual Meeting Demonstrating Potential for Pan-Cancer Utility of DetermalO™

Mar 15, 2021

-Results achieved in metastatic bladder cancer suggests Oncocyte's DetermalO test may be a strong predictor of Immune Checkpoint Inhibitor (ICI) therapy response in a third cancer type in addition to lung and breast cancer -

-Data provides support for potential clinical use of Oncocyte's DetermalO test across multiple solid tumors as predictor of response to ICI therapy in estimated \$3 billion market -

IRVINE, Calif., March 15, 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, will be presenting new data at the American Association for Cancer Research (AACR) Annual Meeting 2021, held virtually from April 10-15, 2021. The presentations will feature data from studies regarding Oncocyte's novel predictor of immune therapy response, demonstrating the potential for the applicability of its gene expression test across multiple cancers.

Oncocyte will present two studies, one in a poster session and a second selected for a podium presentation. The poster will detail translation of the DetermalO™ algorithm to metastatic bladder cancer. The podium presentation will demonstrate DetermalO's strong performance in identifying responders to immune-checkpoint inhibitors as measured by overall survival rates in DetermalO positive patients who received immune-checkpoint inhibitors. These results complement Oncocyte's previously presented data in lung and breast cancer, expanding cancer types for which the test may be applicable, and suggesting a potential pan-cancer role for Oncocyte's DetermalO gene expression test.

"We are encouraged by the results of these new studies which were conducted on bladder cancer as they provide support for the use of DetermalO to identify patients across multiple cancer types that will best respond to immunotherapies," said Robert S. Seitz, Head of IO Technology at Oncocyte, and one of the developers of DetermalO. "Additionally, the immune checkpoint inhibitor used in the bladder cancer clinical study, atezolizumab (Tecentriq®), marks the fourth different immune checkpoint inhibitor with which DetermalO has shown promising results, the others being pembrolizumab (Keytruda®), nivolumab (Opdivo®), and durvulumab (Imfinzi®), encouraging our belief that DetermalO shows promise not only as a pan-cancer marker but is also associated with response to multiple therapeutics directed at different checkpoint targets."

There are an estimated 750,000 patients potentially eligible for immuno-oncology (IO) therapy in the US annually, and nearly 5,000 clinical trials currently evaluating these drugs, but there is a need for more accurate predictive biomarkers for immunotherapy response prediction. The Company believes the

potential pan-cancer utility of DetermalO ideally positions Oncocyte to participate in what Grand View Research estimates to be a \$3 billion IO response testing market by 2026.

Oncocyte will host a KOL webinar on April 19th at 11:30 am EDT/8:30 am PDT to present these results. The presenters will be: Mamta Parikh, MD, MS, Assistant Professor at UC Davis Comprehensive Cancer Center, a medical oncologist who specializes in the treatment of genitourinary malignancies including kidney, bladder, prostate, ureteral cancers, and Dr. David Gandara, MD, Professor – Emeritus and Director of the Thoracic Oncology Program at the UC Davis Comprehensive Cancer Center. Additional details on the event and the link to the webinar will be made available in late March.

The poster and oral presentations and related details are highlighted below:

Presentation Title:

[Pathway modeling to translate the 27-gene immuno-oncology algorithm into bladder cancer](#)

Authors: Robert S. Seitz (presenter), Tyler J. Nielsen, Brock L. Schweitzer, David R. Hout, Douglas T. Ross, Oncocyte Corporation

Abstract Number: 175

Session Title: PO.BSB01.02 - Application of Bioinformatics to Cancer Biology

Session Date and Time: Saturday, April 10, 2021, 8:30 AM EDT - 11:59 PM EDT

Session Type: Poster Presentation

Links to the poster presentation will be available [here](#) beginning at 8:30 AM US EDT on Saturday, April 10. Posters will be available for viewing to meeting registrants until Monday, June 21.

Summary:

Researchers used a novel bioinformatics approach developed by Oncocyte to determine whether the 27-gene algorithm was classifying the Tumor Microenvironment (TME) in metastatic urothelial carcinoma (mUC), or bladder cancer in a way that was consistent with what had been previously seen in breast and lung. The dramatic separation of tumors expressing a “hot”, inflammatory signature as opposed to a “cold” immune repressive signature, supported the application of the TME gene expression signature to the study of immune response therapeutics in bladder cancer without changing either the algorithm or the classification thresholds

Presentation Title:

[Validation of a 27-gene immuno-oncology algorithm in metastatic urothelial carcinoma treated with an immune checkpoint inhibitor](#)

Authors: Robert S. Seitz (presenter), Douglas T. Ross, Tyler J. Nielsen, David R. Hout, Brock L. Schweitzer, Oncocyte Corporation

Abstract Number: 23

Session Title: MS.CL01.01-Biomarkers

Session Date and Time: Saturday, April 10, 2021, 1:50 PM EDT – 2:00 PM EDT

Session Type: Mini Symposium Presentation.

Summary:

These data demonstrate DetermalO’s association with response to ICI therapy in a third and new tissue indication, mUC or advanced bladder cancer, in addition to Triple Negative Breast Cancer (TNBC) and non-small cell lung cancer (NSCLC) along with a fourth different ICI agent. The algorithm and classification threshold were established prior to testing in all three studies (see summary of poster presentation

above) and was not changed between the different tissue indications. Taken together, these data begin to establish the 27-gene DetermaIO as a pan-cancer predictor of response to ICI therapy.

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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 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 data presented at the 2021 American Association for Cancer Research (AACR) Annual Meeting, 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.

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