Oncocyte Announces Publication of the Validation of DetermaIO in Predicting Immune Therapy Response in Metastatic Bladder Cancer

Aug 24, 2022

IRVINE, Calif., Aug. 24, 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, today announces the peer-reviewed publication evaluating the performance of DetermaIO™ in metastatic urothelial (bladder) cancer treated with the immune checkpoint inhibitor (ICI), Tencentriq® (atezolizumab). The results were published in the Journal of Translational Medicine [August 16, 2022].

The IMvigor210 clinical trial treated 429 patients with Tencentriq, and the ICI was approved under an accelerated approval pathway. However, this approval was withdrawn for those patients who had previously failed platinum therapy based on a follow-up ICI therapeutic trial which failed to achieve significance, even if stratified by the standard biomarker, PD-L1 IHC. The results of the newly published biomarker study showed that DetermaIO identified 40% of the 348 patients available for DetermaIO biomarker analysis as likely responders, and that they had a median survival of 15.6 months compared to 8.8 months without biomarker stratification. At two years, 41.5% of DetermaIO-positive patients were alive versus 28.6% in the population as a whole.

“This peer-reviewed publication demonstrates our approach to translating DetermaIO to a novel tissue type, including validating its performance as a classifier on a new tissue type, validating the existing algorithm and threshold as a TIME classifier, and then validating DetermaIO as an ICI response predictor on the precious clinical trial samples,” commented Dr. Doug Ross, Chief Science Officer at Oncocyte. “This approach demonstrated that DetermaIO outperformed previously published gene expression signatures and additional conventional biomarkers, which supports its superior clinical utility in bladder cancer and keeps us on track for a CMS submission this fall.”

Highlights of the peer-reviewed publication include:

- Clinical Validation of DetermaIO as a predictor of response to ICI Therapy in a large clinical trial population of 348 metastatic bladder cancer patients, a tissue where DetermaIO had not previously been tested.

- DetermaIO outperformed nineteen other genomic signatures and additional existing biomarkers originally selected for testing.

- Continued evidence supports the thesis that DetermaIO has utility across multiple cancer types.

- The potential for DetermaIO to help inform the use of immune checkpoint inhibitor therapy for advanced bladder cancer.

- Illustration of how DetermaIO captures a broad portrait of the complex tumor immune microenvironment useful for diagnostic and therapeutic development.

“We have always maintained the strength of DetermaIO is the fact that it looks at three key components of the tumor immune microenvironment, a hot signature, and two cold signatures, leading to DetermaIO’s successful validation as an ICI response predictor across six tissue types to date,” said Rob Seitz, Head of Immune Oncology and Bioinformatics at Oncocyte. “We continue to be encouraged by the repeated success of DetermaIO independent of tumor type or immune therapy tested.”

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. Through its proprietary tests and pharmaceutical services business, the Company 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™ is a gene expression test that 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, DetermaCNI™, a blood-based monitoring test, DetermaMx™, a long-term recurrence monitoring test, and VitaGraft™, a blood-based solid organ transplantation monitoring test. 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 VitaGraft™ are trademarks of Oncocyte Corporation. DetermaIO™ was developed and its performance characteristics determined by Oncocyte.

Tencentriq® is a registered trademark of Genentech, Inc.

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 expectation of a CMS submission this fall, 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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Source: Oncocyte Corporation

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