Oncocyte's DetermaIO Immuno-Oncology Assay Predicts Response to Atezolizumab in Phase 2 Clinical Trial

Oct 08, 2024

Results published in peer-reviewed journal, Clinical Cancer Research

Study validates DetermaIO's utility in identifying breast cancer patients most likely to benefit from atezolizumab

DetermaIO targets a multi-billion-dollar addressable market in oncology diagnostics

IRVINE, Calif., Oct. 08, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corp. (Nasdaq: OCX), a diagnostics technology company, announced the peer-reviewed publication of positive data related to its proprietary gene expression test, DetermaIO™.

The NeoTRIP Phase 2 clinical trial (NCT002620280) randomized patients with triple-negative breast cancer (TNBC) to receive neoadjuvant carboplatin and nab-paclitaxel (chemotherapies to shrink tumors), with or without the immunotherapy, atezolizumab. As a secondary point of interest in the study, Oncocyte's DetermaIO test was among several established biomarkers and gene signatures assessed for its ability to predict which patients with early stage TNBC are most likely to benefit from the immunotherapy. The study was performed in collaboration with the Michelangelo Foundation for Cancer Research, a well-regarded independent scientific organization based in Milan.

There is an unmet need in TNBC for biomarkers that are predictive of the selective benefit of immune checkpoint inhibitors, which DetermaIO aims to address. Only DetermaIO was both statistically significant and predictive of a pathologic complete response (pCR) among the various biomarkers assessed. In the NeoTRIP clinical trial, patients who tested positive by the DetermaIO assay (IO+) had a significantly higher pathologic complete response (pCR) rate when treated with atezolizumab plus chemotherapy (69.8%) compared to chemotherapy alone (46.9%). In contrast, patients who tested negative by the DetermaIO assay (IO-) did not show a significant improvement in pCR rates with atezolizumab plus chemotherapy (44.6%) compared with chemotherapy alone (49.2%), highlighting DetermaIO's predictive power for the selective benefit of immune checkpoint inhibitors, or ICIs.

"We are thankful for the support from Dr. Matteo Dugo and his team, and are thrilled that the data in this clinical trial and this publication clearly demonstrate that DetermaIO can identify patients who are more likely to benefit from immunotherapy," Oncocyte CEO Josh Riggs said. "DetermaIO continues to outperform standard of care biomarkers and assays. A 69.8% response rate in the treatment arm for IO+ patients is fantastic and consistent with previous studies. We will add this study to our submission to CMS (Centers for Medicare and Medicaid Services) and continue our push for CMS reimbursement coverage so that we can broaden access to this valuable test. I also expect this result and the forthcoming

data from a separate 800+ patient study exploring additional indications in TNBC to support our ongoing DetermaIO partnering conversations."

The data from the NeoTRIP clinical trial related to DetermaIO is published in the scientific journal, Clinical Cancer Research, and validates the direction of Oncocyte's research and development pipeline, which is designed to drive sustained rapid growth over the next decade. Oncocyte's mission is to democratize access to molecular diagnostic testing to improve patient outcomes. The company is investing in developing products to serve the separate verticals of organ transplant testing and oncology. Oncocyte is presently commercializing its transplant product line, which includes the VitaGraft™ and GraftAssure™ tests. Specifically, GraftAssure is being launched globally with the support of Bio-Rad Laboratories, a leading diagnostics equipment company. Oncocyte also expects to begin commercializing its oncology product line, which includes DetermaIO, over the next 18 months.

The published study further demonstrates DetermaIO's effectiveness in predicting which patients may selectively benefit from immune checkpoint inhibitors

TNBC is an aggressive form of breast cancer that does not respond to typical hormonal or targeted therapies and is often treated with systemic therapy, such as chemotherapy and immunotherapy. Oncocyte's DetermaIO test is a novel gene expression assay that measures the expression levels of 27-genes to assess various components of the tumor immune microenvironment.

The NeoTRIP study demonstrated DetermaIO's ability to predict which patients will most likely benefit from adding an immune checkpoint inhibitor (ICI) to their therapy regimen.

Highlights of the publication include:

- Among PD-L1 IHC, sTILs and 11 immune signatures analyzed, *only* DetermaIO was significant for interaction, meaning it could predict which patients were most likely to achieve pathologic complete response (pCR), specifically by adding atezolizumab to chemotherapy.

- As noted above, patients receiving a DetermaIO-positive (IO+) result had a significantly higher pathologic complete response (pCR) rate when treated with atezolizumab plus chemotherapy (69.8%) compared to chemotherapy alone (46.9%). DetermaIO-negative (IO-) result patients did not show improved pCR rates with the addition of atezolizumab compared to chemotherapy alone (44.6% vs 49.2%). The interaction test between DetermaIO and the treatment arm was statistically significant (P-value = 0.043).

- In an unselected patient population, the addition of atezolizumab achieved a numerically higher pCR rate (48.6%) but did not show a significant improvement over the chemotherapy-only arm (44.4%) in patients with TNBC.

- The predictive value of DetermaIO was further validated using gene expression data from the pembrolizumab + chemotherapy and the chemotherapy-alone arms of the I-SPY2 Trial (NCT01042379). DetermaIO-positive patients experienced a significantly higher pCR rate with pembrolizumab (IO+ = 85.7%; IO- = 46.7%, p=0.04). No significant association was found in the chemotherapy alone arm (IO+ and IO- = 16%, p=0.99). The analysis from the I-SPY2 study was reported for the first time in the context of the NeoTRIP study.

About Oncocyte

Oncocyte is a diagnostics technology company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a clinical blood-based solid organ transplantation monitoring test. GraftAssure™ is a research use only (RUO) blood-based solid organ transplantation monitoring test. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. DetermaCNI™ is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients. For more information about Oncocyte, please visit https://oncocyte.com/. For more information about our products, please visit the following web pages:

VitaGraft Kidney™ - https://oncocyte.com/vitagraft-kidney/VitaGraft Liver™ - https://oncocyte.com/vitagraft-liver/GraftAssure™ - https://oncocyte.com/graftassure/DetermaIO™ - https://oncocyte.com/determa-io/DetermaCNI™ - https://oncocyte.com/determa-cni/

VitaGraft™, GraftAssure™, DetermaIO™, and DetermaCNI™ 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 development and commercialization of Oncocyte's oncology product line, which includes DetermaIO, over the next 18 months, the company's planned CMS submission for reimbursement coverage for DetermaIO, the ongoing global launch of GraftAssure with the support of Bio-Rad Laboratories, 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, 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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