Oncocyte Presents DetermaIO™ Data in Podium Presentation at ESMO World Congress on Gastrointestinal Cancer 2022

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Researchers conducted exploratory analysis to find an optimized IO score after validation of original established endpoint was presented at the 2022 ASCO Annual Meeting

DetermaIO may help to predict benefit of immunotherapy for the 95% of patients with colon cancer currently ineligible for treatment based on existing biomarker

IRVINE, Calif., July 06, 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 announced that DetermaIO™, the Company's proprietary test designed to determine the likelihood of benefit of immune checkpoint inhibitors (ICIs), was featured in a podium presentation at the European Society of Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2022, held in Barcelona, Spain from 29 June-2 July, 2022. The presentation will include a summary of DetermaIO's performance in the AtezoTRIBE cohort for metastatic colorectal cancer as well as present new exploratory data with the same study.

After the Company validated its established endpoint for the DetermaIO test at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, investigators from the AtezoTRIBE study conducted an exploratory analysis of the trial data to identify patients who would derive maximal benefit from receiving immunotherapy in addition to chemotherapy by establishing an optimized IO score cut-point (IO^{OPT}), adopted to dichotomize tumors as IO^{OPT+} or IO^{OPT-}.

The AtezoTRIBE study previously demonstrated that the addition of the ICI Tecentriq (atezolizumab) benefited some patients with metastatic colorectal cancer (mCRC), but that the current biomarker, which identifies only about 5% of those with colon cancer, misses a significant fraction of responders. For the other 95% of patients, those with proficient mismatch repair (pMMR) tumors, identifying a subgroup able to achieve benefit from ICIs is an urgent unmet need. As part of the validation data presented at ASCO 2022, researchers assessed the role of DetermaIO to predict clinical benefit from the addition of an ICI to first-line chemotherapy in patients with mCRC, finding that 27% of patients in this study were DetermaIO positive. Identification of these patients had a significant association with progression free survival (PFS) regardless of whether they were in the pMMR group or not.

"We believe that metastatic colorectal cancer is a terrific opportunity for DetermaIO to become a CDx for ICI therapy given there is a very large patient population who today have no access to IO therapy," said Ron A Andrews, CEO of Oncocyte. "While early, we have identified a patient population that will benefit from immune therapy and provide a chance to extend life expectancy where today there is very little hope. To date, we have repeatedly shown that DetermaIO's assessment of the Tumor Microenvironment

is predictive of response across multiple solid tumor types and across the four top Immunotherapies on the market today. Dr. Antoniotti's presentation is further validation of a previous study in mCRC, and provides supporting evidence for further studies that may expand DetermaIO to its fourth validated tumor type for CMS submission."

The ESMO GI oral presentation, titled **An immune-related gene expression profile predicts the efficacy of adding atezolizumab to first-line FOLFOXIRI/bevacizumab in metastatic colorectal cancer: a translational analysis of the phase II randomized AtezoTRIBE study**, highlights how researchers found that within the unstratified cohort of patients from AtezoTRIBE, IO^{OPT+} tumors more frequently had a high amount of tumor mutational burden and longer PFS. When stratifying by treatment arm, IO^{OPT+} tumors saw significantly higher PFS for patients who received chemotherapy plus immunotherapy versus those who received chemotherapy alone.

Based on these results, researchers concluded that the optimized, exploratory threshold may help to predict benefit from the addition of immunotherapy to chemotherapy in colon cancer, even within the 95% of patients with pMMR tumors, as was seen in the data presented by the Company at ASCO.

"This exploratory analysis is an exciting build upon previously validated data for DetermaIO," said Carlotta Antoniotti, Assistant Professor of Internal Medicine at the University of Pisa. "Identifying a subgroup of pMMR patients able to achieve benefit from treatment with an ICI is a crucial challenge of translational research, and we look forward to further exploring the optimized IO cut points in independent metastatic colorectal cancer cohorts."

DetermaIO was launched via an Early Access Program in Q4 of 2021 and is the first and only commercial test to assess multiple components of the tumor immune microenvironment (TIME), giving insight into the biology of the tumor that allows for physicians and their patients to make informed decisions about their treatment journey. Data from Oncocyte to date show that the test identifies patients who respond to ICIs – including Keytruda®, Opdivo®, Tecentriq® and Imfinzi® – in lung, bladder, kidney, triple-negative breast, colon, and gastric cancers, suggesting a pan-cancer utility for the test in both primary and metastatic settings.

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.

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, expectations related to DetermaIO, such as the opportunity in metastatic colorectal cancer for DetermaIO to become a CDx for ICI therapy, 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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