DetermaIO™ Clinical Test to be used in SWOG Cancer Research Network Biomarker Study for Breast Cancer

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IRVINE, Calif., Oct. 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 has been selected by the SWOG Cancer Research Network, an independent global cancer research community that designs and conducts publicly funded clinical trials, to be used in a prospectively designed biomarker study of breast cancer tissues. These tissues were collected during the S1418 Phase III randomized clinical trial of Keytruda® (pembrolizumab) in primary triple negative breast cancer (TNBC).

S1418 is a clinical trial conducted by SWOG and sponsored by the National Cancer Institute. The trial enrolled triple negative breast cancer (TNBC) patients who were treated with standard of care preoperative chemotherapy and still had residual cancer that could be detected after chemotherapy at the time of breast surgery. Patients with cancer that measured >1 cm and/or had positive lymph nodes were randomized for observation or one year of treatment with Keytruda®.

“We are excited to partner with Oncocyte to test DetermaIO in the S1418 trial,” said Lajos Pusztai, MD, principal investigator. “Identifying specific patient populations who benefit from postoperative pembrolizumab is important because of the autoimmune side effects that these drugs could cause and the substantial costs involved. Targeting therapy to those who need it is the key promise of predictive biomarkers.”

DetermaIO was selected by SWOG as part of a grant proposal to the NCI's Biomarker, Imaging, and Quality of Life Studies Funding Program. This was a highly competitive process open to all cancer types and trials supported by the NCI's Cancer Therapy Evaluation Program. To qualify for the biomarker submission, the assay needed to be technically and clinically validated, and therefore ready for clinical use. The submissions were reviewed by an independent scientific review committee of the NCI.

DetermaIO will become a defined secondary endpoint for the ongoing clinical trial. If successful, the study will support the use of DetermaIO to identify patients who received standard pre-operative chemotherapy, that would likely benefit from a year of Keytruda® treatment after surgery.

“Over their 66-year history, SWOG clinical trials have changed the standards of cancer care by providing unbiased, well powered clinical studies to validate prescriptive outcomes that inform patient management guidelines,” said Rob Seitz, Head of Immune Oncology at Oncocyte. “To be partnered with SWOG, in a prospectively designed biomarker study in a large, randomized clinical trial, marks a major milestone for DetermaIO.”

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.

Keytruda® is a registered trademark of Merck

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 expectation that study will support the use of DetermaIO to identify patients who received standard pre-operative chemotherapy, that would likely benefit from a year of Keytruda® treatment after surgery, 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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