Oncocyte Announces Collaboration with Gruppo Oncologico del Nord Ovest to Evaluate Oncocyte's DetermaIO Test in Colorectal Cancer, the Second Leading Cause of Cancer Mortality Globally

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Gruppo Oncologico del Nord Ovest, a Leading European Clinical Trials Group, Conducts Independent Investigator-Sponsored Clinical Trials for Pharmaceutical Targeted and Immune Therapies

If Successful, Oncocyte's DetermaIO Test for Immune Therapy Response Prediction Will Be Validated in a Fifth Tumor Type, Strengthening the Potential for Pan-Cancer Utility

IRVINE, Calif., June 03, 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, today announced a strategic collaboration with Gruppo Oncologico del Nord-Ovest (GONO Foundation*)* of Pisa, Italy to evaluate DetermaIO™, Oncocyte's proprietary gene expression test that assesses the tumor immune microenvironment from a biopsy sample, as a biomarker for immunotherapy response in metastatic colorectal cancer (mCRC). This is the fifth tumor type being evaluated for DetermaIO which has previously demonstrated the ability to predict immune therapy response in four different cancer types: lung, breast, bladder and renal cancers.

GONO Foundation conducts research in oncology, designing clinical studies which improve the management of patients affected by solid tumors, and is currently conducting several investigator-sponsored randomized trials in colorectal cancer comparing various therapeutics with the current standard of care, including the utility of immune checkpoint inhibitors, a class of immune therapies. These randomized clinical trials are accompanied by biomarker studies designed to distinguish patients who are responders to immune therapy from those patients who are non-responders, making GONO the ideal collaborative partner for Oncocyte.

Chiara Cremolini, M.D., Ph.D, President of the GONO Foundation and Assistant Professor at the Department of Translational Research, University Hospital of Pisa, said, "With the growing body of promising data presented on DetermaIO to determine immunotherapy response for several other cancer indications, we welcome our collaboration with Oncocyte in our clinical studies. Determining which metastatic colorectal cancer patients not bearing microsatellite instability who are currently excluded from immune therapy, but who may benefit from this treatment option, will be a very important milestone in treatment of this devastating disease. We look forward to presenting data from this study at a future scientific meeting."

"We are honored to have been selected to partner with the GONO Foundation in their clinical trial and biomarker strategy with this important opportunity to test the clinical performance of DetermaIO in metastatic colorectal cancer, one of the leading causes of cancer deaths around the world," said Doug

Ross, M.D., Ph.D., Chief Science Officer of Oncocyte. “DetermaIO has been able to effectively predict immunotherapy response in the four tumor types studied to date and we are excited to expand the reach of DetermaIO to a fifth indication. We look forward to working with Dr. Cremolini’s group to define DetermaIO’s role in colorectal cancer which ultimately may provide further support for a pan-cancer applicability of DetermaIO in predicting response to immune checkpoint inhibitor therapy.”

Heinz-Josef Lenz, M.D., FACP, Associate Director for Clinical Research and Co-Leader of the Translational Science Program at the USC Norris Comprehensive Cancer Center, and member of Oncocyte’s Medical Advisory Board said, “I believe that DetermaIO is going to be an important and clinically useful biomarker in identifying responders to immune-therapy, and the clinical evidence generated so far is very exciting. DetermaIO takes a comprehensive biological approach by assessing the tumor microenvironment, which is why it is able to add incremental utility beyond the markers we currently utilize for immunotherapy treatment selection. As a physician treating colorectal cancer, it would be valuable for me to be able to offer immunotherapy to more patients. GONO Foundation and Dr. Cremolini are highly respected in the world of immune-oncology and the collaboration with Oncocyte is timely and important. If DetermaIO can successfully identify additional patients who would respond to IO therapy but are not indicated by the MSI marker, this would become another significant step in supporting its pan-cancer clinical utility.”

Colorectal cancer is the third most common cancer worldwide, with an estimated 1.9 million worldwide cases and 935,000 deaths in 2020, ranking it third in terms of occurrence and second in terms of mortality of all cancers, according to the American Cancer Society. In the U.S. alone, there were an estimated 147,950 cases in 2020, and 53,200 deaths. While immune therapies are approved for this tumor type in patients who are positive for the microsatellite instability biomarker (MSI), only 5% to 10% of metastatic colorectal patients are found to be positive for this biomarker, which means there may be other patients who would respond favorably to immunotherapy but are missed by the MSI biomarker.

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™ in the second half of 2021 as a test to assess mutational status of a tumor to help identify the appropriate targeted therapy. The Company recently completed the acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor (to be rebranded as DetermaCNI) and TheraSure™ Transplant Monitor test, which are both available for clinical research use in EU, 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 a full suite of molecular testing services to support the drug development process for pharmaceutical companies that are developing new cancer treatments.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation, and TheraSure™ is a trademark of Chronix Biomedical, Inc.

About Gruppo Oncologico del Nord-Ovest (GONO Foundation).
Gruppo Oncologico Nord-Ovest (GONO) is a scientific association of medical doctors and researchers, aiming at contributing to the development of clinical research and study design in the field of clinical

oncology. This cooperative group was formed in 1987 with the purpose of promoting independent research in Italy, i.e. investigator- and not company-driven research projects.

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 DetermaIO gene expression test in the colorectal clinical trials, including its potential use and efficacy, potential addressable market sizes, 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 our or our 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 our 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, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we or our subsidiaries commercialize, 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 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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