Oncocyte and Fondazione Michelangelo, a Leading Non-Profit Cancer Research Foundation, Announce Immune Therapy Biomarker Collaboration

Oct 08, 2020

Investigator-sponsored trial to evaluate DetermaIO™ as a biomarker of neoadjuvant checkpoint inhibitor response in triple-negative breast cancer (TNBC)

Collaboration to generate near-term pharmaceutical services revenue for Oncocyte, and may facilitate a path to U.S. clinical launch in 2H2021

IRVINE, Calif., Oct. 08, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: 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 *the Fondazione Michelangelo* (FM) in Milan, Italy to evaluate DetermaIO™ as a biomarker for response in the NeoTRIPaPDL1 trial (NCT02620280). The biomarker trial is a prospectively designed, retrospective study of archived study material from the therapeutic trial in triple-negative breast cancer (TNBC), one of the new frontiers for immune therapy treatment.

At recently held scientific conferences, The Society for Immunotherapy of Cancer (SITC) Annual Meeting 2019 and American Society of Clinical Oncology Annual Meeting (ASCO) 2020, researchers from the West Clinic and MD Anderson Cancer Center, respectively, presented results on the predictive performance of DetermaIO in response to PD-1 therapies in advanced non-small cell lung cancer (NSCLC) and TNBC. In these initial studies, the test outperformed the two currently available biomarkers, PD-L1 and TMB, most commonly used to inform patient selection for immunotherapy.

Dr. Luca Gianni president of FM said, “The data presented at both ASCO and SITC are very promising and suggest that DetermaIO may enable the identification and selection of TNBC patients who are most likely to benefit from checkpoint inhibitors. We continue our pursuit of a definitive biomarker for the appropriate selection of patients for immune therapy in TNBC and are enthusiastic about our new collaboration with Oncocyte. We are very hopeful that DetermaIO’s ability to comprehensively assess the tumor microenvironment will improve patient stratification and, ultimately, contribute to better tailored administration of immune-checkpoint therapy.”

“We are excited to be partnering with Fondazione Michelangelo as we seek to establish the clinical validity of DetermaIO in TNBC, a form of breast cancer where patients have minimal options to impact clinical outcomes,” said Dr. Doug Ross, Chief Medical Officer of Oncocyte. “Based on the success of our previous studies with checkpoint inhibitors in TNBC, we believe that the comprehensive information provided by the DetermaIO gene expression signature, when compared to current patient selection strategies, will enable more appropriate identification of patients who are expected to be most responsive to IO treatment.”

Ron Andrews, CEO of Oncocyte, added, “This relationship adds to our growing list of partners and expands our ongoing work in patient stratification for TNBC and NSCLC clinical trials. These types of partnerships are strategically important to expanding the use of DetermaIO and are one of our four revenue growth engines that we believe will lead to our increasing revenue growth over time. Oncocyte sees significant opportunity for DetermaIO to penetrate the potential ~$3B testing market for immunotherapy patient selection. In the U.S. alone, it is estimated that approximately 750,000 solid tumor patients may be eligible to receive immunotherapies, yet no robust test is available to clearly identify which patients are most likely to benefit from these costly therapeutics. The interest in DetermaIO from prestigious researchers like the team at the Fondazione Michelangelo is indicative of momentum that could drive the test to the clinical market possibly as soon as late 2021.”

DetermaIO is Oncocyte’s proprietary gene expression signature test that evaluates the tumor immune microenvironment from a biopsy sample. The test stratifies patients according to their likelihood of responding to immunotherapy. Currently, DetermaIO is available for biopharma diagnostic development and research use only. The Company believes it has significant potential for use as a companion test to select patients for clinical trials and, ultimately, as a full companion diagnostic for clinical use with immunotherapies in patient management.

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’s proprietary tests and pharmaceutical services aim to 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 driving the growth of its revenue. Oncocyte recently launched DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint inhibitor immunotherapies. The Company’s pharmaceutical services help pharmaceutical companies to develop new cancer treatments, some of which may be linked to Oncocyte’s diagnostic tests.

DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

About Fondazione Michelangelo

Fondazione Michelangelo is a scientific non-profit organization for advancement in cancer research and treatment. It was founded by the internationally renowned leading oncologist Gianni Bonadonna in December 1999, and was officially recognized as a non-profit organization by the Italian Government in March 2001. The headquarters of the Fondazione are in Milan, Italy.

The main aims of Fondazione Michelangelo are in the areas of research and education
- To promote and independently conduct new research projects to improve therapeutic options in hematological and solid tumors
- To translate the clinical and therapeutic results into clinical practice and favor their widest availability and applicability
- To share the know-how on designing and conducting clinical and translational studies with third parties

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 commercial launch of DetermaRx, development of DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with 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 financial and operational results, risks inherent in the development and/or commercialization of potential 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 our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater than estimated allocations of resources to develop and commercialize technologies, or 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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