Oncocyte Agrees to Enter Licensing and Collaboration Agreement with Chronix Biomedical

Oct 01, 2020

Chronix's blood-based test monitors the effectiveness of immunotherapy drugs in clinical trials, and potentially in patients receiving immunotherapy treatment

Further extends Oncocyte's product portfolio across the continuum of cancer care by adding important liquid biopsy application

Accelerates the launch of Oncocyte's DetermaRx™ test into Germany and other EU markets

IRVINE, Calif., Oct. 01, 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 that it has agreed to enter a licensing and collaboration agreement with Chronix Biomedical. Oncocyte is licensing Chronix's patented CNI Monitor technology for the TheraSure™-CNI MONITOR clinical assay. This liquid biopsy diagnostic uses copy number instability (CNI) to sensitively quantify the cell-free DNA from the primary solid tumor in a patient's blood. As part of the collaboration, Chronix will use its proven laboratory network in Germany to accelerate the EU market commercial launch of Oncocyte's DetermaRx™.

The agreement will allow Oncocyte to increase its test portfolio in the U.S. to address a broader care continuum. It expands the Company's suite of offerings beyond its currently commercially available tests – DetermaRx™, for chemotherapy treatment selection, and DetermaIO™, for immunotherapy treatment selection. Specifically, the TheraSure-CNI MONITOR test will launch Oncocyte into the market for therapeutic response monitoring, which follows treatment selection in the cancer care continuum. Therapeutic response monitoring includes immunotherapy response monitoring, a market opportunity that independent estimates have projected may approach $15 billion by 2025.

"Adding Chronix's CNI technology and intellectual property furthers Oncocyte's emergence as a leader in comprehensive cancer management and presents an entry point into the therapy monitoring market. By identifying early resistance of a tumor to immune therapy drugs, this technology could provide useful information that may allow physicians to rapidly adjust patients' therapies to optimize the immune system's power to fight cancer. The rapid expansion of immune therapy options presents many choices for physicians. Thus, quickly assessing the effectiveness of therapies can be a game-changer for patients," said Ron Andrews, Chief Executive Officer and President of Oncocyte. "This agreement will materially accelerate our opportunity for growth as an emerging leader in the molecular diagnostic landscape for lung cancer as well as other solid tumors. It not only significantly expands our total available market and allows us to offer an additional high-value test to the same physician prescribers, but also adds a fourth revenue growth engine to our three current revenue growth engines—DetermaRx, DetermaIO, and our

pharma services business. In addition, we expect Chronix's proven laboratory network in Germany will accelerate our launch of DetermaRx in the EU, building upon the rapid initial commercial adoption of DetermaRx in the U.S. over the last several months.

The tumor-naïve CNI technology patented by Chronix assesses cancer patients' blood to quantify the concentration of specific DNA sequences associated with cancer. These concentrations are presented as a CNI score. Measuring changes in CNI scores over cancer treatment can help assess cancer patients' response to therapy in real-time. Other ctDNA based approaches require the sequencing of tumor biopsy tissue upfront to identify patient-specific mutations tracked in blood. CNI MONITOR is a "liquid biopsy" that needs no tissue sample. Avoiding the need to sequence tissue biopsy samples may save valuable healthcare dollars. In addition, tissue biopsy sample can be unavailable or insufficient for genomic testing, particularly in lung cancer, where 15%-30% of patients have inadequate tissue for genomic testing.

Commenting on the licensing agreement and collaboration, Chronix's CEO and Chief Medical Officer Dr. Ekkehard Schuetz said, "We are extremely excited about this cooperation with Oncocyte in immunotherapy for cancer patients. The combination of Oncocyte's DetermaIO as a best-in-class pre-therapeutic predictor of efficacy and Chronix's TheraSure-CNI MONITOR as a validated test for individual therapy success provides the most comprehensive solution to an unmet need for cancer patients. This unique combination has the potential to aid doctors in making better-informed treatment decisions, ensuring that patients get the best working therapy for them personally, and could result in significant cost saving for global health care systems."

Mr. Andrews concluded, "We believe this important collaboration will allow us to drive oncologist adoption and loyalty by combining our treatment selection tests with the Chronix CNI monitoring test. For the first time, using a single report, oncologists will be able to select an appropriate treatment for their patients and monitor patient response to make timely treatment changes. The addition of this test will also further our strategic vision to create a valuable global database with longitudinal patient data across multiple cancer types, positioning Oncocyte as an attractive partner for pharma and other molecular diagnostic companies."

Chronix's technology platform is covered by 12 granted U.S. and EU patents in 7 patent families. The Company has published numerous peer-reviewed papers in leading journals in the field of cell-free DNA diagnostics. Published papers include the use of its tumor cfDNA technology across 11 different cancers, such as lung, breast, and pancreatic cancer in patients who were undergoing radiology, chemotherapy, or immunotherapy treatment, demonstrating broad clinical utility.

Chronix has a well-established laboratory in Germany and a commercial footprint in the EU. Chronix's EU base of laboratory operations, commercial relationship with its clinical lab partner, and relationships with the payor market facilitate DetermaRx's commercial launch into the European market. Plans for DetermaRx's swift EU market entry and reimbursement build upon the test's rapid early adoption since its U.S. market launch in January.

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 company 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 company services help pharmaceutical companies to develop new cancer treatments, many of which may be linked to Oncocyte's diagnostic tests.

DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

About Chronix Biomedical

Chronix Biomedical, Inc. is a U.S.-based molecular diagnostics company developing blood tests for use in cancer treatment and organ transplantation. Chronix's TheraSure™ CNI Monitor for cancer uses proprietary algorithms to derive a copy number instability (CNI) score from the sequencing of circulating cell-free tumor DNA (cfDNA), which can be used in the prognosis, diagnosis and monitoring of therapeutic response to cancer. Chronix TheraSure™ Transplant Monitor quantifies the amount of graft derived cell-free DNA in organ recipients to detect early rejection of organ transplants and better assess the transplant health. Chronix Biomedical has operations in the U.S. & Germany, and the commercial launch of their products began in the EU in 2018.

TheraSure is a trademark of Chronix Biomedical Inc.

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.

Investor Contact

Bob Yedid
LifeSci Advisors, LLC

646-597-6989
bob@lifesciadvisors.com

Media Contact
Cait Williamson, Ph.D.
LifeSci Communications, LLC
646-751-4366
cait@lifescicomms.com

Chronix Investor & Media Contact:
John DiPietro
408-960-2307
jdipietro@chronixbiomedical.com

Source: Oncocyte Corporation