Oncocyte Announces Definitive Agreement to Acquire Chronix Biomedical, Inc.

Feb 02, 2021

Transaction includes proprietary IP and technology for blood-based immune therapy monitoring and for transplant rejection testing

Novel, patented copy number index (CNI) therapy monitoring test developed by Chronix complements Oncocyte's proprietary DetermaIO™ test for immunotherapy treatment selection and may significantly expand the market opportunity for the Company

IRVINE, Calif., Feb. 02, 2021 (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 entered into an agreement to acquire, through a subsidiary, Chronix Biomedical, a privately held molecular diagnostics company developing blood tests for use in cancer treatment and organ transplants. Under the agreement, which supersedes the previous collaboration agreement between the companies announced in October 2020, Oncocyte will acquire the intellectual property (IP) and technology for Chronix's TheraSure™-CNI Monitor, a patented, blood-based test for immune-therapy monitoring, as well as the IP for Chronix's organ transplant technology. Further, Chronix's development and business team will become part of the Oncocyte R&D Team and will maintain lab operations in Germany to support the continued development and commercial launch of the monitoring tests. The EU-based team will also lead Oncocyte's commercial efforts with DetermaRx™ and DetermaIO™ in Germany and other EU member countries upon closing of the transaction.

Cancer modifies the normal genome of cells by accumulating mutations and variation in the number of copies of genes in the genome. The proprietary CNI test developed by Chronix quantitatively measures the amount of that copy number variation (CNV) present in blood that has been shed by dying tumor cells. Monitoring the change in CNI over time for patients on therapy allows a physician to monitor response or progression and adjust treatment accordingly. Oncocyte intends to accelerate further development of the CNI test, which is already supported by peer-reviewed publications, as the Company prepares to launch the test for research use and pharma trials in the second half of 2021. The initial focus will be on clinical studies in lung cancer and other solid tumor types treated by immunotherapy. The Company believes the addition of the CNI test will enable it to enter into blood-based immune-therapy monitoring, which has an estimated Total Available Market of over $3 billion in the United States alone.

"Having worked very closely with Chronix over the past few months we gained greater insight into, and performed more analysis of, the overall potential of Chronix's IP," said Ron Andrews, Chief Executive Officer and President of Oncocyte. "After our evaluation, we believe that acquiring Chronix, whose technology includes 12 granted U.S. and EU patents across seven patent families, provides us with a strong patent portfolio that can serve as the basis for our blood-based therapy monitoring and

recurrence monitoring programs, and ultimately create significant value for Oncocyte. The acquisition also establishes a footprint in the EU for our Company and access to an incredibly talented team with years of development experience in blood-based testing for cancer therapy and transplant rejection. We anticipate the first application of the CNI test to be for immune-therapy monitoring, which will add another component to our capabilities in the immunotherapy setting, providing a comprehensive solution when used along with DetermaIO™ immunotherapy response prediction. While we expect DetermaIO to play an incredibly important part in the immunotherapy diagnostic story, monitoring resistance to checkpoint inhibitors through the CNI test would fill a tremendous unmet need. With between 40%-60% of patients failing to see a sustained respond to immune checkpoint inhibitors, we estimate that by 2025, more than $60 billion a year could be misspent on treatments that may never benefit patients. Identifying these patients early may enable oncologists to make a timely change in therapy management, potentially improve patient outcomes, and provide significant savings in unnecessary health care costs. We look forward to integrating and working with the Chronix team to extend the patent estate which we believe will establish Oncocyte as a leader in the emerging targeted and immune therapy monitoring market. We expect this acquisition to create a strong competitive advantage in the market that will be beneficial to the medical community, payors and patients, as well as to our shareholders."

A study published on the Chronix CNI test in ***Clinical Cancer Research***, "Tumor Cell-Free DNA Copy Number Instability Predicts Therapeutic Response to Immunotherapy", showed 92% predictive value for disease progression prior to cycle two of therapy (at 6 weeks) and close to 100% prediction prior to cycle three (9 weeks), including timely identification of hyper-progression which affects as much as 20% of lung cancer patients on immunotherapy. This data is indicative of the utility of Chronix's patented CNI test as a blood-based test to identify tumor resistance to therapy significantly earlier than imaging alone and may serve an important role in assisting physicians treating cancer patients with knowledge that could lead to better patient outcomes.

Dr. Ekkehard Schuetz, CEO and Chief Medical Officer of Chronix said, "One of the key benefits of the TheraSure-CNI Monitor test is that it does not require tissue upfront. Obtaining biopsy tissue for testing can be very challenging in certain tumor types, particularly in lung cancer with 15-30% of patients not having enough tissue to complete molecular testing. Our publications demonstrate that detection of changes in CNV load is remarkably accurate in detecting disease progression on therapy. It is suitable for monitoring patients being treated with chemotherapy, targeted therapy or immunotherapy. With DetermaIO and the CNI Monitoring test, the combined company will provide a comprehensive solution that addresses two of the biggest challenges in the field of immune therapy: determining those who will best respond early in the patient management cycle, and monitoring for failure to respond and development of resistance. We had the great privilege of working closely with the Oncocyte team over the past few months and believe that together we have the opportunity to build upon the patent estate and further our footprint in therapy monitoring and cancer recurrence monitoring."

Continuing, Mr. Andrews stated, "Gaining the Chronix technology moves us closer to our goal of establishing Oncocyte as the 'go-to' choice for oncologists treating patients with immune therapy and for biopharma companies who need to select the appropriate patients for immunotherapy clinical trials. By offering the combination of DetermaIO and the CNI test, we will become the only company with diagnostic tests that can identify patients for immunotherapy treatment and then also be able to monitor the patients' responses to those treatments in real time, before tumor resistance can be seen in imaging, two integral components of patient management. Our next step is to conduct a definitive prospective study that will allow us to bring the CNI test to market, first in Germany and the EU, and eventually in the US once reimbursement is achieved. Once launched, we expect to drive significant market share advantage among oncologists in the US and EU."

About the Proposed Merger and Principal Transaction Terms

Upon closing, Oncocyte will deliver closing consideration of $2.675 million in cash and $1.5 million of Oncocyte common stock (or approximately 295,000 shares) and will assume liabilities not to exceed $5.5 million. The agreement also provides for Oncocyte to pay a revenue share on the net collected revenues for certain tests and services for specific periods, and to pay a combination of cash or Oncocyte common stock of up to $14 million if certain milestones are achieved. The closing of the merger is subject to a number of conditions, including approval of the transaction by Chronix shareholders, and is expected to be completed by April 30, 2021. Oncocyte intends to deliver shares that may be sold following the closing pursuant to an effective Registration Statement. Additional information regarding the terms of the transaction will be provided in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or about February 5, 2021.

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 recently 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™, a test to assess mutational status of a tumor to help identify the appropriate targeted therapy, in the second half of 2021. The Company also continues with the development of DetermaMx™ as the company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx and DetermaTx are trademarks of Oncocyte Corporation.

About Chronix Biomedical

Chronix Biomedical, Inc. is a privately held, 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 concerning, but not limited to, the proposed acquisition of Chronix Biomedical and the effects of the merger, which has not yet closed. 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. Factors that could cause or contribute to changes in the forward-looking statements include, but are not limited to (i) failure to realize the anticipated benefits of the acquisition, (ii) unexpected expenditures or assumed liabilities that may be incurred as a result of the

acquisition, (iii) unanticipated difficulties in conforming business practices, including accounting policies, procedures, internal controls, and financial records of Chronix with Oncocyte, (iv) inability to accurately forecast the performance of Chronix resulting in unforeseen adverse effects on Oncocyte's operating results, (v) failure to satisfy the conditions to the completion of the acquisition on the anticipated schedule, or at all, (vi) synergies between Chronix and OncoCyte being estimates which may be materially different from actual results, (vii) failure to retain or integrate Chronix personnel, (viii) greater than estimated allocations of company resources to develop and commercialize Chronix technologies, (ix) failure to maintain any laboratory accreditation or certification, or (x) failure of Chronix shareholders to approve the merger. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our or any distributor's 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 or any distributor's supply chain, 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 commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality 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
656-751-4366
cait@lifescicomms.com

ONCOCYTE™

Source: Oncocyte Corporation