Oncocyte and Burning Rock Execute Strategic Agreement to Distribute DetermaRx in China

Dec 15, 2020

Aligns Oncocyte with one of China's fastest growing NGS-based cancer therapy selection companies; China is considered to be the world's largest early-stage lung cancer market

Exclusive agreement includes payments of up to $6M in the first year and ongoing per test fees

IRVINE, Calif., Dec. 15, 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, has signed an exclusive agreement in China to license DetermaRx™, its proprietary test to identify high-risk, early-stage lung cancer patients who need treatment to improve their five-year survival, to Burning Rock Biotech Limited, a $2.5 billion market cap NASDAQ-listed (BNR) company. Burning Rock is one of the fastest growing and largest companies in China's next-generation sequencing (NGS) based cancer therapy selection market.

Under the agreement, Oncocyte will receive upfront cash payments after transferring and installing DetermaRx technologies, and for a fixed number of tests performed when DetermaRx achieves inclusion in the United States National Comprehensive Cancer Network (NCCN) Guidelines. Oncocyte will also receive ongoing royalties per patient tested with DetermaRx. The transfer of the testing technology is scheduled to occur in the first quarter of 2021, and the technology installation is expected to be completed by the third quarter of 2021.

China represents the largest patient population in the world for DetermaRx. This agreement marks Oncocyte's fifth global licensing agreement and completes the Company's stated goal of reaching all the major world markets within the first year of launch.

DetermaRx is a treatment stratification test that identifies stage I-IIA non-small cell lung cancer (NSCLC) patients at high-risk of recurrence despite ostensibly curative surgery, who may benefit from the addition of chemotherapy. The test is reimbursed by Medicare. In a 250-patient prospective cohort, test-identified, low-risk patients had a five year freedom from recurrence (FFR) rate of 94.6%; test-identified high-risk or intermediate-risk patients who were treated with adjuvant platinum chemotherapy had 96.7% five year FFR compared to 71.7% five-year disease-free survival (DFS) for high-risk patients who did not receive chemotherapy. Recurrence rate in molecular high-risk stage IA patients was 25%, compared to only 3% in molecular low-risk stage IA patients.[1]

"This agreement with Burning Rock accelerates the ongoing expansion of our DetermaRx test to patients and physicians outside the U.S., and exemplifies our global growth strategy," said Ron Andrews, Chief Executive Officer and President of Oncocyte. "We believe aligning with one of the largest and fastest growing companies in China's NGS-based cancer therapy selection market speaks to the strength of

DetermaRx as a valuable treatment stratification tool to help clarify this critical treatment decision point in early stage tumors. We continue to see strong growth in all of our commercial metrics thus far in the fourth quarter, and this agreement helps us achieve our goal of completing distribution agreements for DetermaRx in all major rest-of-world markets within one year of the U.S. product launch. We are honored to partner with Burning Rock whose comprehensive portfolio of molecular tests for the oncology market allows us access to the largest eligible patient population in the world as well as China's major cancer centers. In addition to expanding our available market, this important milestone also provides us with non-dilutive capital and an ongoing revenue stream to strengthen our growth trajectory as well as help reduce our operational cash burn."

Yusheng Han, Founder and Chief Executive Officer of Burning Rock added, "We are excited to be entering into this agreement with Oncocyte. As the leader of NGS application in oncology in China, we are committed to providing the best diagnostic solutions to Chinese patients and oncologists. China's stage I-IIA non-squamous NSCLC incidence is estimated at over 100,000 per annum[2]. We believe Oncocyte's risk stratification test fills a clear unmet need in identifying those patients who are at high risk and may benefit from adjuvant chemotherapy, versus low risk patients who do not have to undergo unnecessary chemo treatments, in a convenient and affordable manner. Combining DetermaRx with our products for genetic testing and MRD detection (currently under R&D), we can provide a comprehensive testing strategy for oncologists to ultimately benefit Chinese early-stage NSCLC patients by improving their survival and quality of life. We look forward to expanding this much-needed and promising test to the Chinese market and continuing to collaborate with Oncocyte in the future."

For a more complete description of the terms of the agreement, please read the Exclusive Sublicense Agreement that will be filed as an exhibit to Oncocyte's Form 8-K on or about December 14, 2020.

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. The Company also plans to launch monitoring tests including Therasure™-CNI MONITOR, a blood-based immune therapy monitoring test, as a research use tool in 2021. 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 and DetermaIO are trademarks of Oncocyte Corporation. Therasure is a trademark of Chronix Biomedical Inc.

About Burning Rock

Burning Rock Biotech Limited (NASDAQ: BNR), whose mission is to guard life via science, focuses on the application of next generation sequencing (NGS) technology in the field of precision oncology. Its business consists of i) NGS-based therapy selection testing for late-stage cancer patients, with the leading market share in China and over 185,000 tissue and liquid-based tests completed cumulatively, and ii) cancer early detection, which has moved beyond proof-of-concept R&D into the clinical validation stage.

For more information about Burning Rock, please visit: www.brbiotech.com.

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 timing and success of the technology installation plan or commercial launch of DetermaRx in China, unexpected delays, unexpected expenditures, indemnities or other liabilities, or other unanticipated difficulties resulting from technology transfers, commercial plans, invalidation, termination or reduction of any licensed intellectual property rights, or infringement of third party intellectual property rights, acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte or any distributor, 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 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.

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[1] Woodard et al., 2020 North America International Association for the Study of Lung Cancer Conference Poster

[2] Shi JF et al., Clinical characteristics and medical service utilization of lung cancer in China, 2005-2014: Overall design and results from a multicenter retrospective epidemiologic survey. Lung Cancer. February

2019. See also: the NCDB database, available at https://www.facs.org/quality-programs/cancer/ncdb.

Source: Oncocyte Corporation