Oncocyte and Burning Rock Complete Technology Transfer Part Two and Prepare for Scaled Distribution of DetermaRx™ in China

Dec 08, 2021

Companies complete second and most critical of three steps in Technology Transfer Oncocyte receives $2M milestone payment

IRVINE, Calif., Dec. 08, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer, today announced the completion of the second part of the technology transfer under its revised Exclusive Sublicense Agreement with Burning Rock Biotech Limited (Burning Rock), an industry leader for next generation sequencing (NGS)-based precision oncology testing in China. Per the agreement, Burning Rock has licensed Oncocyte's proprietary risk stratification DetermaRx™ test in China, and is now poised to launch the test to the world's largest early-stage lung cancer market.

Under the terms of the revised Exclusive Sublicense Agreement, Oncocyte has achieved part two of the three-part technology transfer, which enables Burning Rock to launch the DetermaRx risk stratification test commercially. This part of the technology transfer included validation that DetermaRx test results achieved in Oncocyte's diagnostic laboratory can be reproduced in Burning Rock's diagnostic laboratories. Burning Rock intends to launch the test across its laboratory network in China, where the patient population that might benefit from DetermaRx is approximately 5 to 6 times larger than that of the US.

The DetermaRx test is used to identify high-risk, early-stage lung cancer patients who are most likely to benefit from treatment to improve their five-year survival.

"The challenge of completing a tech transfer of a complex molecular diagnostic RNA signature in the midst of a global pandemic cannot be minimized. Yet, the two companies remained steadfast in their commitment to the goal of delivering our life-saving test to cancer patients in China and kept the program on track throughout the last 12 months," said Ron Andrews, President and Chief Executive Officer of Oncocyte. "Burning Rock is a leader in China for NGS-based precision oncology testing, and our collaboration with the Burning Rock team was a natural fit to ensure access to the world's largest eligible patient population, and China's major cancer centers as a part of Burning Rock's impressive and comprehensive portfolio of molecular tests. As we progress to the next part of our agreement, we look forward to scaling the distribution of our novel test in China in the first quarter of 2022."

Part three of the technology transfer, and its associated $1 million milestone payment to Oncocyte, involves Burning Rock's validation of updated reporting software, designed to enable scaling of testing and reporting, as well as delivery of standardized reference material needed to satisfy anticipated demand in China. Under the revised agreement, Oncocyte is scheduled to deliver the user guides and

reference material to Burning Rock by the end of January 2022. The milestone payment to Oncocyte is subject to Burning Rock confirming completion of this final part of the technology transfer by April 30, 2022.

Joe Zhang, CTO of Burning Rock commented, “We are excited to have substantially completed the transfer of DetermaRx™ to our lab and are grateful for the productive partnership with Oncocyte to enable access to this important test for patients in China. China's stage I-IIA non-squamous NSCLC incidence is estimated at over 100,000 per annum[1]. 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 therapy. The validation data for DetermaRx™ included clinical studies in China which is critical for market adoption. We look forward to bringing this product to Chinese patients in the near future.”

About Oncocyte

Oncocyte is a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company’s tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research-use only tool, assesses the tumor microenvironment to predict response to immunotherapies. The Company’s pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, blood-based monitoring test DetermaCNI™, and long-term recurrence monitoring test DetermaMx™. In addition, Oncocyte’s pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

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

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, among other things, the expected satisfactory delivery of DetermaRx software user guides, reference materials, and other information required to fulfill the technology transfer requirement by April 20, 2022, the scaled distribution of DetermaRx by Burning Rock, the expectation that DetermaRx will achieve a significant level of acceptance in lung cancer treatment in China, 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 Oncocyte or its 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 Oncocyte’s 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, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients’ use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, 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 (SEC) 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.

Media Contact

Megan Kernan
Westwicke/ICR Healthcare PR
Tel: **646.677.1870**
Megan.Kernan@westwicke.com

Investor Contact

Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

[1] Shi JF et al., Clinical characteristics and medical service utilization of lung cancer in China, 2005-2014: Overall design and results from a multi-center retrospective epidemiologic survey. Lung Cancer. February 2019. See also: the NCDB database, available at https://www.facs.org/quality-programs/cancer/ncdb.

ONCOCYTE™

Source: Oncocyte Corporation

Powered by SITECORE