Burning Rock Announces an Exclusive in-Licensing of a Risk Stratification Test for Early Stage Lung-Cancer Patients from Oncocyte in China

December 15, 2020

GUANGZHOU, China, Dec. 15, 2020 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the “Company” or “Burning Rock”) today announced that it entered into an exclusive licensing agreement with Oncocyte Corporation (NYSE American: OCX) to bring DetermaRx™, a risk stratification test for early stage lung cancer patients, to China.

Even though early-stage non-small-cell lung cancer (NSCLC) generally demonstrates a good prognosis after surgery, a significant proportion of early-stage NSCLC patients suffer from fast relapse, which is generally attributable to metastatic disease undetected at complete resection. Management of such patients depends on prognostic staging to identify the individuals most likely to have occult disease. DetermaRx is a treatment stratification test that identifies stage I-IIA non-squamous NSCLC patients at high-risk of recurrence despite ostensibly curative surgery, who may benefit from the addition of chemotherapy. The test was originally developed at the University of California, San Francisco, in a cohort of 361 patients with non-squamous NSCLC. The assay was then independently validated in a masked cohort of 433 patients with stage I non-squamous NSCLC at Kaiser Permanente Northern California hospitals, and an independently recruited cohort of 1006 patients with stage I–III non-squamous NSCLC from multiple leading Chinese cancer centers.[1] In a 250-patient prospective cohort, test-identified low-risk patients had a 5-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% 5-year FFR compared to 71.7% 5-year 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. In addition, the assay is independent of EGFR mutation status, and effectively segregates high- and low-risk patients among those with both EGFR wildtype and mutant tumors. [2] The test received final Medicare LCD from Palmetto in April 2020.

“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 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.[3] 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.”

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: ir.brbiotech.com.

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 has also launched DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint inhibitor immunotherapies, for research and pharma clinical trial use. 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.

Safe Harbor Statement

This press release contains forward-looking statements. These statements constitute “forward-looking” statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and as defined in the U.S. Private Securities Litigation Reform Act of 1995. These forward-

looking statements can be identified by terminology such as “will,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” “target,” “confident” and similar statements. Burning Rock may also make written or oral forward-looking statements in its periodic reports to the SEC, in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about Burning Rock’s beliefs and expectations, are forward-looking statements. Such statements are based upon management’s current expectations and current market and operating conditions, and relate to events that involve known or unknown risks, uncertainties and other factors, all of which are difficult to predict and many of which are beyond Burning Rock’s control. Forward-looking statements involve risks, uncertainties and other factors that could cause actual results to differ materially from those contained in any such statements. All information provided in this press release is as of the date of this press release, and Burning Rock does not undertake any obligation to update any forward-looking statement as a result of new information, future events or otherwise, except as required under applicable law.

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[1] Kratz et al., A practical molecular assay to predict survival in resected non- squamous, non-small-cell lung cancer: development and international validation studies. Lancet. March 2012.

[2] Woodard et al., Molecular risk stratification is independent of EGFR mutation status in identifying early-stage NSCLC patients at risk for recurrence and likely to benefit from adjuvant chemotherapy. 2020 North America International Association for the Study of Lung Cancer Conference Poster.

[3] 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.