



Burning Rock Received FDA Breakthrough Device Designation for its OverC™ Multi-Cancer Detection Blood Test

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IRVINE, Calif., Jan. 03, 2023 (GLOBE NEWSWIRE) -- Burning Rock (NASDAQ/LSE: BNR), a company focused on the application of next generation sequencing (NGS) technology in the field of precision oncology, today announced that its OverC™ Multi-Cancer Detection Blood Test (MCDBT) has been granted Breakthrough Device Designation by the US Food and Drug Administration (FDA), which is the third of its kind globally.

Under the FDA's Breakthrough Devices Program, the Breakthrough Device Designation is granted to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions such as cancer. This program is designed to provide patients and healthcare providers with timely access to medical devices granted the designation by speeding up their development, assessment, and review.

OverC™ MCDBT is intended for early detection of multiple cancer types (esophageal, liver, lung, ovarian, and pancreatic cancers) in adults of either sex, aged 50-75 years old, at average risk for cancer. OverC™ MCDBT demonstrated a 69.1% of sensitivity and 98.9% of specificity in the case-control study, THUNDER, and will be further validated in prospective interventional studies among asymptomatic population. Test results of "Detected" with the top one or two predicted tissues of origin of cancer-associated signals may indicate the presence of cancer and should be followed up by diagnostic tests suggested by qualified healthcare professionals in accordance with professional guidelines. Test results of "Undetected" do not rule out the presence of cancer, and individuals should continue with guideline-recommended standard of care screening tests.

Compared with conventional cancer screening methods, liquid biopsy has the potential to increase detection efficiency and enable early diagnosis and treatment, thus improving patients' survival and quality of life while reducing social burden of the disease. Burning Rock started development of multi-cancer early detection technology based on DNA methylation in 2016, and the technology and validation data have been presented at [ASCO](#), [ESMO](#) and other medical conferences, as well as journals such as *Nature Biomedical Engineering* ^[1], demonstrating high specificity, sensitivity, and accuracy in predicting the tissue of origin. In May 2022, Burning Rock received CE mark for its OverC™ MCDBT manufactured in both the US and China facilities. Today, the FDA Breakthrough Device Designation granted for OverC™ MCDBT would pave the way for a clearer registration path through confirmative performance validation and utility establishment.

Mr. Yusheng Han, founder and CEO of Burning Rock, said, "We are very excited that our cfDNA methylation multi-cancer early detection technology has received FDA Breakthrough Device Designation. For cancer, early diagnosis and treatment are the key to the long-term survival of patients. Liquid biopsy-based early detection technology will be an important supplement to the current cancer screening methods, especially for ovarian cancer, pancreatic cancer and other cancers that have no effective screening methods up to now. Burning Rock has also launched two prospectively collected case-control studies, PREDICT and PRESCIENT, with more than 10,000 subjects to be enrolled, to continue developing OverC™ MCDBT to cover more cancer types. With our promising clinical research data, we believe that over time our collective effort is going to make significant impact towards the improvement of cancer patients' lifespan and quality of life."

Reference

[1] Liang N, Li B, et al. Ultrasensitive detection of circulating tumour DNA via deep methylation sequencing aided by machine learning. *Nat Biomed Eng.* 2021 Jun;5 (6):586-599.

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, 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.

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