



Burning Rock Received Breakthrough Device Designation from China's NMPA for its Multi-Cancer Early Detection Test

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GUANGZHOU, China, Oct. 15, 2023 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR and LSE: BNR, the "Company" or "Burning Rock") is pleased to announce that followed an earlier Breakthrough Device Designation granted by the US Food and Drug Administration (FDA) for its OverC™ Multi-Cancer Detection Blood Test (MCDBT) in January 2023, its OverC™ MCDBT has been granted Breakthrough Device Designation by the China National Medical Products Administration (NMPA), which represents the only test globally that has received Breakthrough Device Designation from both US FDA and China NMPA.

OverC™ MCDBT is intended for early detection of multiple cancer types 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 achieved a superior tissue traceability capabilities-the prediction accuracy of TPO1 (primary traceability organ) and TPO2 (primary and secondary traceability organs) was 83.2% and 91.7%, respectively. The technology and validation data have been released on *Annals of Oncology* in March 2023, showing an impressive performance of ELSA-seq using cfDNA in cancer detection and origin prediction.

Mr. Yusheng Han, founder and CEO of Burning Rock, said, "We are very inspired that our multi-cancer early detection product has received recognition from both US and China regulatory authorities. We obtained our first Breakthrough Device Designation from China NMPA in 2016 for NGS-based therapy selection test, and the China NMPA Breakthrough Device Designation granted for OverC™ MCDBT would pave the way for a clearer registration path through confirmative performance validation and utility establishment. Burning Rock will actively strive to promote the clinical research process, technological innovation, and industry development."

About Burning Rock

Burning Rock Biotech Limited (NASDAQ: BNR and LSE: 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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