Burning Rock Secures Second NGS Kit Approval from the NMPA

March 15, 2022

GUANGZHOU, China, March 15, 2022 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the “Company” or “Burning Rock”) today announced that the National Medical Products Administration (**NMPA**) approved Burning Rock’s Human Nine-Gene Mutation Joint Detection Kit (reversible termination sequencing) (**LungCure™ CDx**) as a class III medical device. This approval demonstrates Burning Rock's industry-leading capability of working with the NMPA on bringing an innovative next generation sequencing (**NGS**)-based diagnostic product to the China market.

LungCure™ CDx is the Company’s second NMPA-approved NGS-based reagent kit for multiple gene mutation, following our industry-first kit approval in 2018. LungCure™ CDx can be used in *in vitro* detections of genetic variations of EGFR, ALK, ROS1, KRAS, MET, ERBB2, BRAF, PIK3CA and RET genes associated with non-small cell lung cancer (**NSCLC**) patients, three of which (EGFR, ALK and ROS1) are approved under the NMPA standards for companion diagnostics (**CDx**), and provide comprehensive guidance on NSCLC targeted therapy.

LungCure™ CDx has significantly improved the detection capability of rare variant types. It is the first NGS-based reagent kit approved in China which has the ability to detect MET amplification and MET exon 14 skipping. At the same time, LungCure™ CDx has reached a number of CDx development collaborations with well-known pharmaceutical companies.

LungCure™ CDx targets and captures exons and some intron regions of the above nine genes that are highly related to the personalized treatment of NSCLC in NCCN/CSCO Guidelines, covering point mutation, indel, fusion (rearrangement) and amplification. LungCure™ CDx significantly improves the detection performance and detection range of rare genetic variations, such as MET amplification, MET exon 14 skipping, ALK rearrangement, ROS1 rearrangement, RET rearrangement, etc., benefiting more patients clinically.

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 1) NGS-based therapy selection testing for late-stage cancer patients, 2) Global pharmaceutical services on biomarker detection and companion diagnostics developing, and 3) NGS-based 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.

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.

Contact: IR@brbiotech.com