



## Merck KGaA, Darmstadt, Germany and Burning Rock Collaborate on Liquid-biopsy Based CDx Development Using Burning Rock's OncoCompass Target™

November 18, 2021

GUANGZHOU, China, Nov. 17, 2021 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the "Company" or "Burning Rock") today announced a strategic partnership with Merck KGaA, Darmstadt, Germany, in companion diagnostics (CDx) development for the *MET* inhibitor tepotinib in the mainland China market. The CDx test is based on Burning Rock's self-developed next generation sequencing (NGS)-based liquid biopsy solution, OncoCompass Target™ panel.

Tepotinib is an oral *MET* inhibitor that inhibits the oncogenic *MET* receptor signaling caused by *MET* (gene) alterations. Discovered and developed in-house at Merck KGaA, Darmstadt, Germany, tepotinib has a highly selective mechanism of action, with the potential to improve outcomes in aggressive tumors that have a poor prognosis and harbor these specific alterations. Tepotinib was the first oral *MET* inhibitor to receive a regulatory approval anywhere in the world for the treatment of advanced non-small cell lung cancer (NSCLC) harboring *MET* gene alterations, with its approval in Japan in March 2020 under the brand name TEPMETKO®. In February 2021, the U.S. Food and Drug Administration granted accelerated approval to TEPMETKO, making it the first and only once-daily oral *MET* inhibitor approved for patients in the U.S. with metastatic NSCLC with *MET*ex14 skipping alterations. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Tepotinib is available in a number of other countries, and under review by various regulatory authorities globally.

Burning Rock's OncoCompass Target™ is a self-developed NGS-based testing panel. This panel, being as the only invited product from China, participated in the SEQC2 (sequencing quality control phase 2) study, an FDA-led community wide consortium (the MAQC consortium) effort to address issues relating to the application of constantly evolving high-throughput genomics technologies, and achieved strong performance. The study was published on *Nature Biotechnology* in April 2021 (<https://www.nature.com/articles/s41587-021-00857-z>). Burning Rock will continue its efforts on the research and development of tumor genetic testing to benefit more cancer patients with the latest and effective precision medicine solutions.

### About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics. Around 58,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2020, Merck KGaA, Darmstadt, Germany, generated sales of € 17.5 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

### 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, with the leading market share in China and over 273,000 tissue and liquid-based tests completed cumulatively, 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. In July 2018, Burning Rock received the first approval for a tumor NGS kit by the National Medical Products Administration (NMPA), which is a significant milestone in the field of in vitro diagnosis in China. The two laboratories of Burning Rock, which are located in Guangzhou, China and California, U.S., have both obtained the certificate issued by the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA) certificate issued by the Centers for Medicare and Medicaid Services (CMS). The Guangzhou laboratory has also obtained the technical certification of "High-throughput sequencing laboratory" issued by the Guangdong branch of the National Center for Clinical Laboratories (NCCL). The Company is devoted to developing innovative and reliable NGS-based testing products and advancing oncology precision medicine solutions.

For more information about Burning Rock, please visit: [ir.brbiotech.com](http://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