



Burning Rock and IMPACT Therapeutics Announce a Global Strategic Partnership for Companion Diagnostics Development

August 3, 2021

GUANGZHOU, China, Aug. 03, 2021 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the "Company" or "Burning Rock") today announced a global strategic partnership with IMPACT Therapeutics in companion diagnostics (CDx) development for a pipeline of drugs in the field of synthetic lethality. The two companies will jointly develop CDx for a targeted oncology drug, Senaparib (IMP4297), a PARP inhibitor, for the treatment of prostate cancer globally, including CDx submissions to both the U.S. Food and Drug Administration (FDA) and the National Medical Products Administration of China (NMPA). The global program will be supported by Burning Rock's Clinical Laboratory Improvement Amendments (CLIA) certified and College of American Pathologists (CAP) accredited labs in Guangzhou, China and California, U.S. Furthermore, the two companies will deepen collaborations in exploring and discovering new biomarkers for a pipeline of targeted drugs.

Senaparib is a PARP inhibitor developed by IMPACT Therapeutics. A number of Senaparib clinical trials have been conducted globally, including the ongoing Phase III clinical trial of Senaparib monotherapy as the 1st line maintenance treatment in ovarian cancer, the Phase II clinical trial of Senaparib as the 3rd line therapy in the treatment of patients with ovarian cancer harboring BRCA mutation, and phase I/II clinical trial of Senaparib and TMZ combination therapy in patients with advanced solid tumors and small cell lung cancer. Recently, IMPACT Therapeutics has received the approval by the U.S. FDA to initiate a clinical study of IMP4297 in metastatic castration-resistant prostate cancer (mCRPC) treatment. The purpose of this study is to evaluate the efficacy and safety of Senaparib in the maintenance treatment of mCRPC patients with homologous recombination repair (HRR) gene alterations who have not progressed after docetaxel therapy. The multi-regional clinical trial (MRCT) will soon begin in multiple regions, including the U.S. and 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 CAP and the CLIA certificate issued by the Centers for Medicare and Medicaid Services (CMS). The certified laboratories can support global registrational clinical trials of biomarker detection and also the submission of CDx. As the first CDx project filed in the NGS area with concurrent trials in China and the U.S., the partnership will expedite the clinical research program of Senaparib to benefit patients globally.

Dr. Jun Bao, President and CEO of IMPACT Therapeutics said, "Burning Rock's expertise and experience in the field of genetic sequencing will help drive the global development of Senaparib and further accelerate IMPACT Therapeutics' pipeline development in the field of synthetic lethality. By establishing a long-term strategic partnership with Burning Rock, I am confident that there will be a strong synergy which would benefit patients all over the world."

Yusheng Han, Founder and CEO of Burning Rock said, "IMPACT Therapeutics has one of the most diverse drug pipelines in the field of synthetic lethality. The clinical and preclinical data of Senaparib have demonstrated its potential as the leading first-line maintenance therapy for mCRPC patients. Burning Rock and IMPACT Therapeutics have established a long-term strategic partnership for the development of a pipeline of targeted oncology drugs in the field of synthetic lethality and will leverage each other's strengths to develop the corresponding CDx. The oncology drugs and CDx will be launched concurrently to benefit patients with safe and effective therapies."

About IMPACT Therapeutics

IMPACT Therapeutics is a biopharmaceutical company dedicated to the discovery and development of targeted anti-cancer therapeutics based on synthetic lethality. IMPACT Therapeutics has assembled one of the most comprehensive DNA damage response (DDR) global pipeline of novel drug candidates generated by in-house discovery efforts and is expanding to other novel synthetic lethality targets to broaden its pipeline. IMPACT pipeline products include PARP inhibitor (senaparib/ IMP4297), Wee1 inhibitor (IMP7068), and other novel DDR pathway inhibitors. The lead clinical program, PARP inhibitor (senaparib/ IMP4297), is in Phase III study in China, and a global clinical trial-mCRPC study which has received FDA IND approval. Senaparib's preliminary clinical data demonstrated superior tolerability and wider therapeutic window compared with other PARPi. Phase I study of Wee1 inhibitor (IMP7068) is conducted globally.

For more information, please visit www.impacttherapeutics.com

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 273,000 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.

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