NMPA Grants Marketing Approval to the First Co-Developed NGS-Based Companion Diagnostic for Lung Cancer in China

October 10, 2024

GUANGZHOU, China, Oct. 10, 2024 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the “Company” or “Burning Rock”), an innovative company in the field of precision oncology, and Dizal, a global biopharmaceutical company focused on malignant tumors and immunological diseases, jointly announced that the companion diagnostic (CDx) for EGFR exon 20 insertion mutation (exon20ins) for sunvozertinib, developed through their collaboration, has been approved by the National Medical Products Administration (NMPA) of China. This marks the first co-developed NGS-based CDx for lung cancer approved by NMPA since the release of the CDx guideline in China. The approval of this CDx test is the result of the simultaneous development of Burning Rock's independently developed LungCure CDx (a kit for the combined detection of 9 human gene mutations) and Dizal's innovative EGFR exon20ins targeted therapy - sunvozertinib, providing an innovative precision treatment solution for non-small cell lung cancer patients with EGFR exon20ins.

Mr. Yusheng Han, Founder and CEO of Burning Rock stated: "We are thrilled to have carried out a deep companion diagnostic collaboration with the global biopharmaceutical company Dizal. This collaboration sets a standardized and high-quality benchmark for the concurrent development of companion diagnostics for anti-tumor drugs. Burning Rock is strategically positioned to drive companion diagnostic development on a global scale for pharmaceutical companies. By integrating our resources and experience in the field of oncology diagnosis and treatment, we are confident that we can offer more precise treatment options for Chinese cancer patients."

Dr. Xiaolin Zhang, Founder, Chairman, and CEO of Dizal stated: “This achievement can be attributed to the collaborative innovation of the professional teams from both sides and reflects our unremitting pursuit of creating clinical value for the benefit of patients. Precision therapy is one of the core strategies of Dizal. Dizal will continue to adhere to the discovery and development of groundbreaking new medicines, and work with our partners to bring new hope of precision treatment to more patients.”

About Sunvozertinib
Sunvozertinib is an irreversible EGFR inhibitor discovered by Dizal scientists targeting a wide spectrum of EGFR mutations with wild-type EGFR selectivity. In August 2023, sunvozertinib received approval from NMPA to treat advanced NSCLC with EGFR exon20ins after platinum-based chemotherapies. The approval was based on the results of WU-KONG6 study, the pivotal study of sunvozertinib in platinum-based chemotherapy pretreated NSCLC with EGFR exon20ins. The primary endpoint of the study was the confirmed objective response rate (cORR) as assessed by the Independent Review Committee (IRC) reached 61%. Anti-tumor efficacy was observed across a broad range of EGFR exon20ins subtypes, and in patients with pretreated and stable brain metastasis. In addition, sunvozertinib also demonstrated encouraging anti-tumor activity in NSCLC patients with EGFR sensitizing, T790M, and uncommon mutations (such as G719X, L861Q, etc.), as well as HER2 exon20ins. Sunvozertinib showed a well-tolerated and manageable safety profile in the clinic. The most common drug-related TEAEs (treatment-emergent adverse event) were Grade 1/2 in nature and clinically manageable. Two global pivotal studies are ongoing in ≥ second-line (WU-KONG1 Part B) and first-line setting (WU-KONG28), respectively, in NSCLC patients with EGFR exon20ins. Pre-clinical and clinical results of sunvozertinib were published in peer-reviewed journals Cancer Discovery (IF:39.397) and The Lancet Respiratory Medicine (IF: 76.2).

About LungCure CDx
On March 11, 2022, the National Medical Products Administration (NMPA) officially approved the registration of the company's Human Nine-Gene Mutation Joint Detection Kit (reversible termination sequencing) (commercially known as "LungCure CDx") as a Class III medical device product. This test kit is Burning Rock’s second NMPA-approved companion diagnostic multi-gene tumor mutation co-detection test kit based on high-throughput sequencing technology and meeting companion diagnostic standards. It can be used for in vitro detection of multiple mutation statuses of EGFR, MET, ERBB2, KRAS, BRAF, PIK3CA, ALK, ROS1, and RET genes in non-small cell lung cancer patients, including point mutations, insertions/deletions, fusions (rearrangements), amplifications, etc., to comprehensively guide targeted therapy for non-small cell lung cancer.
"LungCure CDx" has undergone rigorous clinical validation, enhancing the detection capability of rare mutation types. At the same time, "LungCure CDx" has entered into companion diagnostics development strategic partnerships with several well-known domestic and international pharmaceutical companies to jointly promote the development of standardized and precise diagnosis and treatment in oncology.

About Dizal
Dizal is a biopharmaceutical company, dedicated to the discovery, development and commercialization of differentiated therapeutics for the treatment of cancer and immunological diseases. The company aims to develop first-in-class and groundbreaking new medicines, and further address unmet medical needs worldwide. Deep-rooted in translational science and molecular design, it has established an internationally competitive portfolio with two leading assets in global pivotal studies, both of which have already been launched in China.
To learn more about Dizal, please visit www.dizalpharma.com, or follow us on LinkedIn or Twitter.

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 development, and 3) Early cancer detection which has moved beyond proof-of-concept R&D into the clinical validation stage. Burning Rock provides dedicated services to pharmaceutical partners, encompassing genomic data solutions, clinical trial solutions, precision patient recruitment, and companion diagnostics development and commercialization. Burning Rock has achieved two NMPA-approved IVD kits, four assays with CE marking, and a breakthrough device designation (BDD) received from both US

FDA and China NMPA for multi-cancer detection blood test.
For more information about Burning Rock, please visit: https://us.brbiotech.com.

Contact: IR@brbiotech.com