BN104 Granted Orphan Drug Designation by US FDA for the Treatment of Acute Myeloid Leukemia

SHANGHAI, China, April. 20, 2023 - BioNova Pharmaceuticals Limited (BioNova), a company dedicated to the discovery, development and commercialization of innovative medicines for the treatment of diseases with unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to BN104 for the treatment of acute myeloid leukemia (AML).

BN104 is a novel, potent and highly selective, oral menin inhibitor and is being investigated as a potential treatment for relapsed/refractory (R/R) leukemia patients with mixed lineage leukemia rearranged (MLLr) or nucleophosmin mutant (NPM1c). It showed excellent efficacy in multiple xenografic models. While head-to-head comparing with other clinical-stage menin inhibitors in preclinical studies, BN104 excelled competitors with a superior safety profile, and a substantially broader therapeutic window.

“We are extremely picky when it comes to set up a home-grown discovery program. BN104 is BioNova’s first in-house discovery project that meets both scientific rationale and high unmet medical needs. The ODD is a testimony from the US FDA to acknowledge BN104’s potential in addressing both.” said Ye Hua, MD, MPH, Founder and CEO of BioNova, “We initiated this menin inhibitor project from scratch about 2 years ago with the aim to discover a best-in-class compound. Today we are very pleased with the BN104’s characteristcs demonstrated in preclinical studies. We are filing investigational new drug (IND) application both in China and US. We will work diligently with health authorities and medical society to expedite BN104 development in clinic and hope to bring this promising agent to patients soon.”

About FDA Orphan Drug Designation

The FDA’s Office of Orphan Products Development grants ODD status to a drug or biological product to prevent, diagnose or treat a rare disease or condition affecting fewer than 200,000 people in the USA. Companies that are granted ODD are eligible for incentives, including tax credits for qualified clinical trials, exemption from user fees and up to seven years of market exclusivity after approval.

About BioNova

BioNova Pharmaceuticals Limited is a privately held clinical-stage biopharmaceutical company dedicated to the development and commercialization of innovative medicines for cancer and other life-threatening diseases with high unmet medical needs. Headquartered in Shanghai, BioNova is a fast-growing company of which robust pipeline is built upon internal R&D programs, collaborations with and acquisitions from partners of cutting-edge technology. With a highly capable and experienced team in combination with substantial funding, BioNova is committed to delivering high-quality innovative medicines to patients in China and globally.

For further information, please refer to https://www.bionovapharma.com.

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