



BioNova Announces FDA Fast Track Designation Granted to BN104 for the Treatment of Acute Leukemia

SHANGHAI, China, Oct. 24, 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 Fast Track Designation (FTD) to BN104 for the treatment of relapsed/refractory (R/R) acute leukemia.

“We are encouraged by receiving FTD for BN104. It is a statement from the US FDA in acknowledging BN104’s therapeutic potential to fill the unmet medical need in patients suffering from life-threatening acute leukemias.” said Ye Hua, MD, MPH, Founder and CEO of BioNova, “BioNova is committed to delivering high-quality innovative medicines to patients in China and globally. BN104 is the first in-house discovery project that is now in clinical stage. We have just initiated Phase 1 clinical trial in September in China and look forward to verifying its therapeutic potential as shown in preclinical studies. We are grateful that with the FTD BioNova will have more frequent interactions with the FDA to expedite BN104 development in the US for patients in needs.”

About BN104

BN104 is a novel, highly selective, potent oral menin inhibitor designed and discovered by BioNova. Menin inhibitors are currently under investigation as a potential treatment for acute leukemias where harbor a mixed-lineage leukemia rearranged (MLLr) or nucleophosmin (NPM1) mutation. BN104 was granted Orphan Drug Designation (ODD) by US FDA in April 2023. BN104 received IND clearance in August and September 2023 in China and US, respectively.

About FDA Fast Track Designation (FTD)

Fast Track Designation (FTD) aims to facilitate the development and expedite the review of new therapeutics that are intended to treat serious or life-threatening conditions and that potentially address an unmet medical need. The purpose is to get important new drugs to the patient earlier. Drugs that are granted this designation are given the opportunity for more frequent interactions with the FDA, as well as potential pathways for expedited 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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