



## **BioNova Announces FDA Clearance of IND Application for BN104 for the Treatment of Acute Leukemia**

SHANGHAI, China, Sep. 21, 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 cleared its Investigational New Drug (IND) application for BN104 for the treatment of relapsed/refractory (R/R) acute leukemia.

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. In preclinical studies, comparing with other clinical stage menin inhibitors, BN104 excelled competitors with excellent efficacy, a superior safety profile, and a significantly broader therapeutic window.

“This is BioNova’s first US IND that indicates our company has grown into a global biotech company with innovative drug being developed outside of China.” said Ye Hua, MD, MPH, Founder and CEO of BioNova, “2023 is the year when BioNova has demonstrated her capability not only in “home-grown” discovery but also of global value. Within the last two months, we successfully received IND clearance for BN104 in China and US, respectively. Looking ahead, we will move forward to unlock the therapeutic potential of BN104 in acute leukemia patients with high unmet medical needs.”

### **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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