



BioNova Submits Investigational New Drug Application for BN104 for the Treatment of Acute Leukemia in China

SHANGHAI, China, May. 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 it has submitted an investigational new drug (IND) application for BN104 for the treatment of relapsed/refractory (R/R) acute leukemia to the China National Medical Products Administration (NMPA).

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 R/R acute leukemia patients who harbor a mixed lineage leukemia rearranged (MLLr) or nucleophosmin (NPM1) mutation globally. 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.

“We are very proud of this achievement as BN104 is our first home-grown project. The filing of BN104 is a monumental statement of BioNova’s capability in both drug discovery and development. Once again, BN104 serves the objective of meeting both scientific rationale and high unmet medical needs.” said Ye Hua, MD, MPH, Founder and CEO of BioNova, “We initiated this potentially best-in-class menin inhibitor project from scratch about 2 years ago. Thanks to our prospective pipeline build-up strategy plus experienced in-house cross-functional discovery team, we have reached this major milestone towards advancing BN104 into clinic. Now with its chemical characteristics and data demonstrated in preclinical studies, we are highly confident and more committed than ever to accelerating BN104 development and to eventually benefiting leukemia patients dying from such disease in the future.”

In April 2023, BN104 received Orphan Drug Designation (ODD) for the treatment of acute myeloid leukemia (AML) by the U.S. Food and Drug Administration (FDA). Meanwhile, BioNova is also working on IND filing to the US FDA in the 3rd quarter 2023.

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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