



BioNova Receives Investigational New Drug Clearance for BN104 for the Treatment of Acute Leukemia in China

SHANGHAI, China, Aug. 14, 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 Center of Drug Evaluation (CDE) of National Medical Products Administration (NMPA) had approved its investigational new drug (IND) application for BN104 for the treatment of relapsed/refractory (R/R) acute leukemia in China.

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 leukemia patients who harbor a mixed-lineage leukemia rearranged (MLLr) or nucleophosmin (NPM1) mutation globally. BN104 has shown best-in-class potential as it excelled competitors with excellent efficacy, a superior safety profile, and a much broader therapeutic window in preclinical studies.

“We are very proud of this achievement as BN104 is our first home-grown project initiated 2 years ago. The IND clearance of BN104 proves BioNova’s capability in both drug discovery and development.” said Ye Hua, MD, MPH, Founder and CEO of BioNova, “We are excited to kick off BN104 clinical development to further investigate its therapeutic effect in acute leukemia patients living with unmet medical need. Thanks to our prospective pipeline build-up strategy plus dedicated cross-functional team, we have finally brought our own discovery project into clinic. The expected first patient dosing in China is targeted in December this year. We will work closely with our study investigators, regulatory agency and the patient community to expedite clinical development in China.”

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 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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