

BioNova Receives Investigational New Drug Clearance for BN102 for the Treatment of Hematologic Malignancies in China

SHANGHAI, China, March. 15, 2022 - 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 BN102 to conduct clinical trials in patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) and B-cell Non-Hodgkin Lymphoma (NHL) in China.

BN102 is a novel next-generation non-covalent Bruton's tyrosine kinase (BTK) inhibitor that is highly selective, orally bioavailable, against both wild type and C481S mutant BTK. Through a licensing agreement with Carina Biosciences Inc. (Carina; JASDAQ: 4572) in March 2020, BioNova gained exclusive rights to develop and commercialize BN102 in Greater China territory, including mainland China, Hong Kong, Macau and Taiwan.

"We are thrilled to initiate clinical trials for BN102 in China shortly after our partner's EU Phase 1 trial. While current 'Gold Standard' therapy for CLL and certain subtypes of B-cell malignancy being the first generation BTK inhibitor, treatment-induced drug resistance becomes a new high unmet medical need." said Ye Hua, M.D., Founder and CEO of BioNova, "This IND clearance is an exciting milestone for BioNova not only because it advanced another pipeline asset to clinical stage, but also demonstrated our excellent cross-functional teamwork and competent execution. We will continuously work with NMPA and the hematology medical society to conduct BN102 clinical trials and to benefit patients living with such unmet medical need in China as soon as possible."

About B-cell Malignancies

B-cell malignancies include chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and B-cell non-Hodgkin's lymphoma (NHL), such as diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL), marginal zone lymphoma (MZL) and lymphoplasmacytic lymphoma/ Waldenström's macroglobulinemia (LPL/WM). In China, 2020 GLOBOCAN reported a total of 92,834 new NHL cases amongst which 75% were B-cell NHLs. There are increasing trends of both incidence and mortality year by year, with 54,351 deaths in 2020, constituting 1.8% of all tumor deaths in China.

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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