



BioNova Announces Submission of Investigational New Drug for BN102 for the Treatment of Hematologic Malignancies in China

Shanghai, China, Jan. 5, 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 it has submitted an investigational new drug (IND) application for BN102 for the treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) and B-cell Non-Hodgkin Lymphoma (NHL) to the China National Medical Products Administration (NMPA).

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

"This IND filing once again demonstrated BioNova cross-functional teamwork and execution, and I'm proud of our team in reaching this challenging goal in the first week of 2022." said Ye Hua, M.D., Founder and CEO of BioNova. "The submission brings another asset into clinical stage for BioNova and allows us to unlock our ambitions in investigating therapeutic potential where the current "Gold Standard" therapy causes acquired resistance in patients suffering from CLL and other B-cell malignancies. While the regulatory work has begun, we are working closely with clinical centers, investigators as well as NMPA to design and conduct clinical trials for the target patient population."

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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