

## **BioNova Receives Investigational New Drug Clearance for BN301 for the Treatment of Hematologic Malignancies in China**

SHANGHAI, China, September. 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 Center of Drug Evaluation (CDE) of National Medical Products Administration (NMPA) had approved its investigational new drug (IND) application for BN301 (STRO-001) to conduct clinical trials in patients with hematologic malignancies in China.

BN301 is a novel target, site-specific antibody-drug conjugate (ADC) comprised of a human aglycosylated anti-CD74 IgG1 antibody and 2 non-cleavable maytansinoid drug-linkers. BN301/STRO-001 was granted Orphan Drug Designation by the US FDA for multiple myeloma in October 2018. Through a licensing agreement with Sutro Biopharma, Inc. (Sutro, NASDAQ: STRO) in October 2021, BioNova gained the option to obtain exclusive rights to develop and commercialize BN301 in Greater China territory, including mainland China, Hong Kong, Macau and Taiwan. STRO-001 is currently being investigated by Sutro in a Phase 1 dose-escalation clinical trial in the US, Israel and Korea with the goal of finding recommended Phase 2 dose.

“This IND clearance of BN301 represents a major milestone for BioNova as not only did we expand our pipeline in hematology but also provided us the opportunity to work on an ADC drug for which the modality is one of the most excited in oncology/hematology.” said Ye Hua, M.D., Founder and CEO of BioNova, “The expected first patient dosing in China is targeted in November this year. Based on its early clinical data in the US, we are strongly encouraged and determined to work closer with our study investigators, regulatory agency and the patient community to get the clinical trial underway. We look forward to fully exploring its therapeutical potential for patients living with such unmet medical needs 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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