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HARBOUR
BIOMED
和 鉑 醫 藥 控 股 有 限 公 司
HBM Holdings Limited
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 02142)

VOLUNTARY ANNOUNCEMENT
HARBOUR BIOMED RECEIVES CHINESE REGULATORY APPROVAL OF
IND APPLICATION TO BEGIN PHASE II CLINICAL TRIAL OF HBM9161
IN CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY
(CIDP)

This announcement is made by HBM Holdings Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that the National Medical Products Administration of the People’s Republic of China (“**China**”) had approved the Company’s investigational new drug (“**IND**”) application for HBM9161, a full-human antibody targeting neonatal Fc receptor (FcRn), to conduct a Phase II clinical trial in patients with CIDP. The IND approval is the fifth for HBM9161 in China.

CIDP is a chronic autoimmune disorder of peripheral nerves and nerve roots caused by an autoimmune-mediated destruction. It is a chronic and progressive disease characterized by progressive weakness and impaired sensory function in the legs and arms and is closely related to Guillain-Barre syndrome. Various epidemiological studies have shown that the prevalence of CIDP in adults may vary from 0.8 to 8.9/100000. Corticosteroid pulses following high dose prednisone maintenance or intravenous immunoglobulin (IVIg) are current standard therapies for patients with CIDP, with an estimated two-thirds of the patients requiring IVIg over many years. Due to the side effects of steroids and limited access to IVIg, there is still high unmet medical needs to explore new, effective and convenient therapies for CIDP.

About Batoclimab (HBM9161)

Batoclimab (HBM9161), a fully human anti-FcRn monoclonal antibodies, blocks FcRn-IgG interactions, accelerating the degradation of autoantibodies and leads to the treatment of pathogenic IgG-mediated autoimmune diseases. Phase II study in myasthenia gravis showed that batoclimab can quickly and significantly alleviate patients’ symptoms and improve quality of life. Earlier studies demonstrated that batoclimab is well tolerated and can rapidly reduce total IgG, in a wide array of pathogenic IgG-mediated autoimmune diseases, including myasthenia gravis, Grave’s ophthalmopathy, neuromyelitis optica spectrum disorder and immune thrombocytopenia, among others.

Cautionary Statement: We cannot guarantee that we will be able to successfully develop or ultimately market batoclimab (HBM9161). Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By order of the Board
HBM Holdings Limited
Dr. Jingsong Wang
Chairman and Executive Director

Hong Kong, 31 August 2021

As at the date of this announcement, the board of directors of the Company comprises Dr. Jingsong Wang and Dr. Mai-Jing Liao as executive Directors; Mr. Yu Min Qiu, Mr. Junfeng Wang and Ms. Weiwei Chen as non-executive Directors; Dr. Robert Irwin Kamen, Dr. Xiaoping Ye and Mr. Ka Chi Yau as independent non-executive Directors.