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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
COMPLETION OF FIRST DOSING OF FIRST PATIENT WITH
BATOCLIMAB (HBM9161) PHASE III TRIAL FOR TREATMENT OF
GENERALIZED MYASTHENIA GRAVIS

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 clinical trial of batoclimab (HBM9161, an anti-FcRn antibody (as defined below)), the novel drug for autoimmune disorder therapy developed by the Company, has completed the first dosing of first patient in registrational phase III trial for the treatment of generalized myasthenia gravis (“**gMG**”). This clinical study aims to assess the efficacy and safety of batoclimab (HBM9161) in patients with gMG in China. It is a subsequent milestone to the announcement of the positive outcome of the first anti-FcRn proof of concept study for the treatment of gMG completed in August 2021. As the first anti-FcRn therapy which achieved clinical evidence in China, data received from the Phase II Study showed a statistically significant and clinically meaningful efficacy of batoclimab, as well as a favorable safety and tolerability profile.

The Company is developing batoclimab (HBM9161) as part of its product pipeline to treat multiple pathogenic-IgG mediated autoimmune diseases with significant unmet medical needs. gMG is among the first of such multiple indications for which the Company is developing drug candidates in China and this therapy received the “Breakthrough Therapy Certificate” from NMPA in early 2021.

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. Available evidence suggests that reduced levels of pathogenic IgG in patients with myasthenia gravis are associated with clinical benefit. 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. The Company licensed batoclimab (HBM9161) from HanAll BioPharma Co., Ltd. and has the right to develop, manufacture and commercialize in Greater China (including Hong Kong, Macau and Taiwan).

About generalized myasthenia gravis

Myasthenia gravis (MG) is an acquired autoimmune disease mediated by antibodies such as anti-acetylcholine receptor (AChR) immunoglobulin G (IgG) antibody and anti-muscle-specific tyrosine kinase (Anti-MuSK) IgG, which involves the postsynaptic membrane of the neuromuscular junction, causes impaired transmission at the neuromuscular junction, and presents with skeletal muscle contraction weakness. Patients often have ocular muscle manifestations, and about 85% of patients will show symptoms other than ocular muscles and develop generalized myasthenia gravis (gMG), some even develop myasthenia crisis.

Current main treatments for MG include cholinesterase inhibitors and glucocorticoids and other immunosuppressive drugs, but the efficacy and safety cannot meet the clinical needs of many patients. Targeting reduction of pathogenic IgG autoantibodies is a pathophysiological mechanism driven solution in MG treatment, such as plasmapheresis and intravenous immunoglobulin, however, there still remains a significant unmet need for these treatment options, including the accessibility, safety and economic cost.

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, 27 September 2021

As at the date of this announcement, the board of directors of the Company comprises Dr. Jingsong Wang and Mr. Xiaoxiang Chen 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.