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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
POSITIVE TOPLINE RESULTS FROM PHASE 2 PROOF-OF-CONCEPT
TRIAL OF BATOCLIMAB (HBM9161) IN 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 positive topline results from interim analysis of its Phase 2 proof-of-concept clinical trial of batoclimab (HBM9161) in Chinese generalized myasthenia gravis (“**gMG**”) patients (the “**Phase 2 Study**”).

Data received from the Phase 2 Study, as the first clinical evidence of anti-FcRn therapies in Chinese patients, showed a statistically significant and clinically meaningful efficacy of batoclimab over placebo, as well as a favorable safety and tolerability profile.

Data from the Phase 2 Study demonstrated that batoclimab has alleviated myasthenic symptoms rapidly with satisfactory safety profile in Chinese patients, supporting batoclimab as a potential novel solution to fill the current treatment gap for gMG patients.

The Phase 2 Study Design

The Trial is a multi-center, double-blinded, placebo-controlled study on 30 subjects suffering moderate to severe gMG to receive batoclimab (340 mg, 10 subjects or 680 mg, 11 subjects) or placebo (9 subjects) once per week for a period of 6 weeks (double blinded treatment period), followed by 340 mg every other week for a period of 6 weeks (open-label treatment period) on a random basis.

The primary efficacy endpoint was the improvement of Myasthenia Gravis Activities of Daily Living (MG-ADL) score from baseline. Secondary efficacy endpoints included the improvements from baseline of Quantitative Myasthenia Gravis (QMG), Myasthenia Gravis Composite (MGC), and Myasthenia Gravis Quality of Life (MG-QoL) score. Other endpoints include safety and tolerability, pharmacokinetics (PK) and pharmacodynamic (PD).

Key Results of the Phase 2 Study

Key results of the Phase 2 Study include: (i) analysis of primary endpoint revealed both 340 mg and 680 mg of batoclimab treatment resulted in rapid, clinically meaningful, and statistically significant improvements over placebo by MG-ADL score reduction from baseline on Day 43 (a week after the last dose of batoclimab ($p = 0.043$); (ii) batoclimab induced rapid, substantial and persistent clinical improvement over placebo as measured by all four predefined clinical efficacy scales – MG-ADL, QMG, MGC and MG-QoL15; (iii) 57%, and 76% of patients in the treatment arm showed persistent clinical improvements (≥ 2 points in MG-ADL and ≥ 3 points in QMG for a period of 6 consecutive weeks) versus 33% in MG-ADL and 11% in QMG in placebo; and (iv) all patients on treatments showed robust IgG reduction (decreased 57% and 74% from baseline on Day 43 in 340-mg and 680-mg groups, respectively) strongly correlated with clinical improvements.

Batoclimab treatment was shown to be overall safe and well-tolerated, with incidence of adverse events (“AE”) comparable to placebo, majority of AEs characterized as mild, no serious adverse events (“SAE”) and no discontinuation due to AEs.

Based on the positive reports of interim analysis of this Phase 2 Study, the Company has already carried out the “end of Phase 2” meeting with Center for Drug Evaluation, National Medical Products Administration (NMPA), and obtained their full support on proceeding to the Phase 3 study. The Company expects that the Phase 3 study will be initiated in the second half of 2021.

About Batoclimab (HBM9161)

Batoclimab (HBM9161), a fully human anti-FcRn mAb, 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 (HBM9161) is well tolerated and can rapidly reduce total IgG. These findings make batoclimab (HBM9161) the first anti-FcRn to demonstrate a sustained IgG reduction in both Chinese and Caucasian populations, when administered via subcutaneous (SC) injection. Batoclimab has been granted “Breakthrough Therapy Designation” by the Chinese NMPA in gMG.

Cautionary Statement: We cannot guarantee that we will be able to successfully develop or ultimately market any of our products referenced in this announcement. 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, 6 July 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.