

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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)

INSIDE INFORMATION
UPDATE ON THE DEVELOPMENT FOR BATOCLIMAB (HBM9161)

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”) of HBM Holdings Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The Company announces that as of the date of this announcement, based on the results of the Phase III clinical trial, which demonstrated that the efficacy in the primary and secondary endpoints of batoclimab (HBM9161), and given the safety profile was favorable and consistent with historical data, the Company has completed the communication with the Center for Drug Evaluation of the National Medical Products Administration of China (the “**NMPA**”) for the biologics license application (“**BLA**”) for batoclimab (HBM9161) for treatment of generalized myasthenia gravis.

In accordance with the clinical trial protocol, the Group is currently in the extension period for the Phase III clinical trial for the collection of other long-term safety data. No additional patients have been enrolled during this extension period. As a result, the Company voluntarily plans to include additional long-term safety data and re-submit the BLA for batoclimab (HBM9161). The Company has been actively communicating with the NMPA regarding the BLA for batoclimab (HBM9161), and subsequent submission-related interactions and processes are currently ongoing. The Company expects to re-submit the BLA for batoclimab (HBM9161) to the NMPA in the first half of 2024.

About Batoclimab (HBM9161)

Batoclimab is designed as a fully human monoclonal antibody that selectively binds to and inhibits the neonatal FcRn. FcRn plays a pivotal role in preventing the degradation of IgG antibodies. High levels of pathogenic IgG antibodies drive many autoimmune diseases. As the most clinically advanced FcRn inhibitor being developed in Greater China, batoclimab has the potential to be a breakthrough treatment for a wide spectrum of autoimmune diseases in Greater China.

Warning under Rule 18A.05 of the Listing Rules: There is no assurance that the batoclimab (HBM9161) will ultimately be successfully marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

Forward-Looking Statements

This announcement may contain certain forward-looking statements that are, by their nature, subject to significant risks and uncertainties. The words “anticipate”, “believe”, “estimate”, “expect”, “intend” and similar expressions, as they relate to the Company, are intended to identify certain of such forward-looking statements. The Company does not intend to update these forward-looking statements regularly. These forward-looking statements are based on the existing beliefs, assumptions, expectations, estimates, projections and understandings of the management of the Company with respect to future events at the time these statements are made. These statements are not a guarantee of future developments and are subject to risks, uncertainties and other factors, some of which are beyond the Company’s control and are difficult to predict. Consequently, actual results may differ materially from information contained in the forward-looking statements as a result of future changes or developments in our business, the Company’s competitive environment and political, economic, legal and social conditions.

The Company, the Directors and the employees of the Company assume (a) no obligation to correct or update the forward-looking statements contained in this announcement; and (b) no liability in the event that any of the forward-looking statements do not materialise or turn out to be incorrect.

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

Hong Kong, 1 December 2023

As at the date of this announcement, the board of Directors of the Company comprises Dr. Jingsong Wang and Dr. Yiping Rong as executive Directors; Ms. Weiwei Chen as non-executive Director; Dr. Robert Irwin Kamen, Dr. Xiaoping Ye, Mr. Ka Chi Yau and Dr. Albert R. Collinson as independent non-executive Directors.