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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)

INSIDE INFORMATION
BIOLOGICS LICENSE APPLICATION FOR BATOCLIMAB (HBM9161)
ACCEPTED BY THE NMPA

This announcement is made by HBM Holdings Limited (the “**Company**”) 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 board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the National Medical Products Administration of China (the “**NMPA**”) has officially accepted the biologics license application for batoclimab (HBM9161) for treatment of generalized myasthenia gravis (“**gMG**”).

On 6 March 2023, the Company announced positive topline results of its Phase III clinical trial of batoclimab (HBM9161) for the treatment of gMG. Result of the Phase III Trial met primary efficacy endpoint as well as key secondary endpoints with a favorable safety profile.

Batoclimab (HBM9161) is a product to treat multiple pathogenic-IgG mediated autoimmune diseases with significant unmet medical needs. gMG is among the first of such multiple indications and this therapy received the “Breakthrough Therapy Certificate” from the NMPA in early 2021 and released the positive topline data of Phase II clinical trial in July 2021. In October 2022, the Company entered into a license agreement with NBP Pharma, a wholly owned subsidiary of the CSPC Group, to advance the development and commercialization of batoclimab in Greater China.

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 clinically most 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, 29 June 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; 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.