

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 ANNOUNCEMENT
NMPA APPROVAL OF BATOCLIMAB INJECTION
(SUBCUTANEOUS INJECTION)
FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS

This announcement is made by 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 the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 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 the People’s Republic of China (the “**NMPA**”) has approved the biologics license application for batoclimab injection (subcutaneous injection) (“**batoclimab SC**”), 170 mg (1 mL)/vial, as an add-on to standard therapy for the treatment of generalized myasthenia gravis (“**gMG**”) in adult patients who are anti-acetylcholine receptor (“**AChR**”) antibody positive (the “**Approval**”). Batoclimab (HBM9161) is a Core Product of the Company under Chapter 18A of the Listing Rules. Batoclimab SC is the first approved product of the Group and the first anti-neonatal Fc receptor (“**FcRn**”) therapy to complete its full clinical development for gMG patients in China.

CLINICAL STUDY RESULTS

The Approval is supported by positive results from a pivotal Phase III clinical study conducted at 27 centres in China. The main study population comprised patients with gMG who were positive for AChR antibodies or muscle-specific tyrosine kinase antibodies. The primary endpoint was the proportion of patients achieving sustained improvement in the Myasthenia Gravis Activities of Daily Living (“**MG-ADL**”) score during the first treatment cycle. Sustained improvement was defined as a reduction of at least three points from baseline in the MG-ADL score that persisted for at least four weeks.

In the study, 58.2% of patients treated with batoclimab SC achieved the primary endpoint, compared with 31.3% in the placebo group (P=0.001). Treatment effect was observed as early as the second week of therapy. The batoclimab SC group also demonstrated statistically significant improvements over placebo in secondary endpoints, including sustained Quantitative Myasthenia Gravis improvement (64.2% versus 40.6%; P=0.008), duration of MG-ADL improvement of at least three points (51.5% versus 36.1%; P=0.008), minimal symptom expression at any visit, defined as an MG-ADL score of 0 or 1 (25.4% versus 4.7%; P=0.004), and sustained MG-ADL improvement in the second treatment cycle (62.7% versus 36.4%; P=0.002).

Batoclimab SC was generally well tolerated. The most frequently reported adverse event in the treatment group was peripheral oedema (38.8% versus 4.6% for placebo), all cases of which were mild to moderate in severity. Plasma albumin levels decreased during treatment and returned spontaneously following treatment discontinuation.

COMMERCIAL ARRANGEMENTS

Pursuant to the license agreement entered into between the Group and NBP Pharma in October 2022, a subsidiary of CSPC Pharmaceutical Group is responsible for the commercialisation of batoclimab in Greater China, comprising Chinese Mainland, Hong Kong, Macau and Taiwan. The Group is entitled to receive tiered royalties based on annual net sales of batoclimab in Greater China.

INFORMATION ABOUT BATOCLIMAB AND gMG

Batoclimab is a fully human monoclonal antibody targeting FcRn. By blocking FcRn-mediated recycling of immunoglobulin G (“IgG”) antibodies, batoclimab accelerates the degradation of pathogenic IgG autoantibodies and provides a targeted therapeutic approach for autoimmune conditions, including gMG. Batoclimab was originally developed by HanAll Biopharma Co., Ltd. (“**HanAll**”) and licensed to Harbour BioMed in 2017 under a strategic collaboration and license agreement. The trade name of batoclimab SC as approved by NMPA is “恩力達”, and the market authorization holder (MAH) of batoclimab SC is Dragon Merit Holdings Limited (佳曦控股有限公司), a subsidiary of CSPC Pharmaceutical Group.

gMG is a rare, chronic autoimmune neuromuscular disorder mediated by antibodies that impair transmission at the neuromuscular junction, resulting in skeletal muscle weakness. The condition can significantly affect patients’ ability to work and quality of life, and severe cases may lead to a potentially life-threatening myasthenic crisis. Existing treatments include cholinesterase inhibitors, glucocorticoids and other immunosuppressive medicines, but unmet needs remain in relation to efficacy, safety, accessibility and cost.

Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that batoclimab will ultimately be successfully marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

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

Hong Kong, 23 October 2026

As at the date of this announcement, the Board comprises Dr. Jingsong Wang, Mr. Youchen Chen and Dr. Ian Yi Liu as executive Directors; and Dr. Robert Irwin Kamen, Dr. Xiaoping Ye, Dr. Albert R. Collinson and Ms. Weiwei Chen as independent non-executive Directors.