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 PHASE II INTERIM RESULTS AND INITIATION OF PHASE III STUDY OF HBM9378/WIN378 IN ASTHMA

This announcement is made by HBM Holdings Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the Company's shareholders and potential investors about the latest business update of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that Windward Bio AG ("**Windward Bio**"), the Company's partner, has reported positive interim results from the Phase II portion of the POLARIS-1 clinical trial of HBM9378/WIN378, a fully human ultra-long-acting monoclonal antibody targeting thymic stromal lymphopoietin ("**TSLP**"), in asthma. The Phase III portion of POLARIS-1 has also been initiated.

HBM9378/WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit TSLP. It was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with the binding of TSLP to both of its co-receptors on the cell surface of epithelial cells.

POLARIS-1 (NCT07120503) is an operationally seamless, global Phase II/III study of HBM9378/WIN378 in adults with uncontrolled asthma conducted by Windward Bio. The Phase II portion of the study is a 48-week, randomised, double-blind study evaluating three dose levels of HBM9378/WIN378 administered subcutaneously against placebo, with primary objectives of characterising pharmacokinetics, safety, immunogenicity and pharmacodynamic activity, as well as informing dose selection for Phase III development. The study also evaluates the effect of HBM9378/WIN378 on lung function and biomarkers of airway inflammation. The Phase II portion enrolled a total of 147 patients, exceeding the initial enrolment target of 120 patients, with the interim analysis conducted on the first 98 patients. The Phase III portion is evaluating two twice-yearly doses of HBM9378/WIN378 against placebo, with a primary endpoint of annualized asthma exacerbation rate in patients with severe asthma.

The interim analysis demonstrated the following at Week 24 after a single dose of HBM9378/WIN378:

(i) Dose-dependent mean increases in forced expiratory volume in one second ("**FEV_1**") of up to 174 mL (placebo-adjusted mean increase up to 256 mL, p = 0.033);

(ii) Dose-dependent mean reductions in fractional exhaled nitric oxide ("**FeNO**") of up to 24 parts per billion (or a 43% reduction; p = 0.006); and

(iii) Reductions in mean blood eosinophil count ("**EOS**") of up to 200 cells/μL (or a 51% reduction; p < 0.0001).

FEV_1 is a key measure of lung function, while FeNO and EOS are key markers of inflammation that correlate with asthma exacerbations. Near-maximal effects were observed as early as Week 2 and sustained through Week 24. The interim analysis demonstrated a half-life of up to 75 days. The interim results and population pharmacokinetic modelling support the potential for twice-yearly dosing of HBM9378/WIN378.

HBM9378/WIN378 was well tolerated, with favorable safety results, and there were no treatment-related serious adverse events, withdrawals or discontinuations observed as of the data cut-off date. Adverse events were balanced between the active treatment arms and placebo. Less than 1% of participants experienced injection site reactions, and 2% developed anti-drug antibodies, a measure of immunogenicity, which had no impact on the pharmacology of HBM9378/WIN378.

Two twice-yearly doses have been selected for the Phase 3 portion of POLARIS-1, which is designed to evaluate the effect of HBM9378/WIN378 on annualized asthma exacerbation rate and other key efficacy measures in patients with severe asthma. The Phase 3 portion of the study has been initiated by Windward Bio who plans to begin a second Phase 3 study, POLARIS-2, in the first half of 2027. Data from the Phase 2 portion of POLARIS-1 will be presented at an upcoming medical congress.

About HBM9378/WIN378

HBM9378/WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit thymic stromal lymphopoietin (TSLP). This clinically validated target plays a key role in the development and progression of a wide array of immunological diseases, including asthma, chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. HBM9378/WIN378 was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with the binding of TSLP to both of its co-receptors on the cell surface of epithelial cells. Phase 2 interim results support the potential of twice-yearly dosing. HBM9378/WIN378 produced significant, sustained and dose-dependent increases in FEV_1, a measure of lung function, together with significant and sustained reductions in FeNO and blood eosinophils — key markers that correlate with asthma exacerbations. HBM9378/WIN378 is being evaluated in the global Phase 2/3 POLARIS-1 study in asthma and the Phase 2 SIRIUS study in COPD, with a second pivotal Phase 3 asthma trial, POLARIS-2, planned to begin in the first half of 2027. HBM9378/WIN378 (also known as SKB378) started as a co-development project jointly conducted by Harbour BioMed and Kelun-Biotech, with both parties equally sharing global rights. Windward Bio licensed the global rights (excluding Greater China and several Southeast and West Asian countries) for this molecule from Harbour BioMed (also known as HBM9378) and Kelun-Biotech (also known as SKB378).

Cautionary Statement: We cannot guarantee that HBM9378/WIN378 will be successfully developed or ultimately marketed by the Company and/or its collaboration partners. Shareholders and potential investors of the Company are advised to exercise due care when dealing with the shares of the Company.

Forward Looking Statement

Forward-looking statements in this announcement, including those concerning the clinical development of HBM9378/WIN378 and the timing of future studies, are subject to risks and uncertainties and may not materialise. Shareholders and potential investors of the Company should not place undue reliance on such statements and should seek professional advice where appropriate.

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

Hong Kong, 8 September 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.