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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 RESULTS FROM PHASE I STUDY AND
ABSTRACTS OF PHASE I DATA OF
NEXT-GENERATION ANTI-CTLA-4 ANTIBODY HBM4003**

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 its latest business updates.

The board of directors of the Company (the “**Board**”) is pleased to announce positive results from its Phase I dose escalation clinical trial HBM4003 in solid tumors in Australia (the “**Phase I Study**”). The clinical data abstracts has been presented by way of an e-poster at the 2021 European Society for Medical Oncology (ESMO) Congress.

The data received from the Phase I Study, as the first clinical evidence of next generation anti-CTLA-4 fully human heavy-chain only antibody (HCAb) in solid tumors, showed favorable safety and encouraging efficacy profile of HBM4003. All treatment-related adverse events (TRAEs) to the extent discovered during the Phase I Study were manageable and reversible. The initial anti-tumor efficacy of HBM4003 monotherapy was encouraging, especially two respondents who underwent multiple therapies responded to HBM4003 monotherapy, and one of whom with advanced liver cancer also received previous PD-1 therapy.

The Phase I Study Design

The Phase I Study 1 is an open-label, multi-center study on subjects with advanced solid tumors to receive HBM4003 at dose levels of 0.3 mg/kg QW (28-day cycle), 0.45 mg/kg Q3W (21-day cycle), and 0.6 mg/kg Q3W (21-day cycle). The primary endpoint for the dose escalation stage is proportion of patients with dose-limiting toxicity (DLT).

Key Results of the Phase I Study

Key results of the Phase 1 Study include:

- (i) 20 patients with advanced solid tumors have been treated at four Australian sites where the Phase 1 Study was conducted, with 13 out of 20 patients (65%) having received 2 or more prior regimens and with 8 patients (40%) having received PD-1 treatment.
- (ii) HBM4003 treatment demonstrated favorable safety profile. No toxicity reported was related to lung, kidney, heart or endocrine system.
- (iii) A dosage of 0.45 mg/kg Q3W was recommended as the phase II dose for dose expansion.
- (iv) A total of 15 patients had post-treatment tumor assessments. One hepatocellular carcinoma (HCC) patient had confirmed partial response (PR) and another prostate cancer patient achieved a PSA response with tumor remaining SD up to 24 weeks. Nine patients had stable disease (SD) with tumor shrinkage in 3 patients.
- (v) For the HCC patient with PR, extended clinical benefit was observed after treatment discontinuation. Tumor reduction reached 64.4% for target lesions and non-target lesions were no longer detectable 16 weeks after the last dose.

About HBM4003

HBM4003 is a fully human anti-CTLA-4 monoclonal heavy chain only antibody (HCAb) generated from Harbour Mice[®]. By enhancing antibody-dependent cell cytotoxicity (ADCC) killing activity, HBM4003 has demonstrated significantly improved depletion specific to high CTLA-4 Treg cells in tumor tissues. The potent anti-tumor efficacy and differentiated pharmacokinetics with durable pharmacodynamic effect presents a favorable product profile. This novel and differentiated mechanism of action has the potential to improve efficacy while significantly reducing the toxicity of the drug in monotherapy and combo-therapy.

Cautionary Statement: We cannot guarantee that we will be able to develop, or ultimately market, HBM4003 successfully. 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, 13 September 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.