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HUA MEDICINE

華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(stock code: 2552)

BUSINESS UPDATE
COMPLETION OF PATIENT ENROLLMENT FOR
PHASE III COMBINATION WITH METFORMIN TRIAL OF DORZAGLIATIN

This announcement is made by Hua Medicine (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders of the Company and potential investors about the latest business updates of the Group.

The Company is pleased to announce the completion of its patient enrollment programme for a Phase III combination trial of dorzagliatin (HMS5552) with metformin, and therefore expects to release the topline results in the second quarter of 2020.

Dorzagliatin is a 3rd generation Type 2 diabetes (T2D) drug candidate, as it has the potential to stop the progression of T2D, which has not been possible with existing drugs on the market. The Phase III trial follows the Group’s Phase II trial design, which demonstrated strong safety and efficacy data, with promising disease modifying effects.

The Phase III combination trial targets metformin-tolerated T2D patients. The combination trial is a double-blind, placebo-controlled study and patients are randomized 1:1 to receive either metformin alone or dorzagliatin combined with metformin. The clinical study evaluates the efficacy and safety of dorzagliatin with 24 weeks of double-blinded treatment plus 28-week open-label treatment, and follow-up. The trial is being conducted in over 70 clinical centres across China.

Upon achieving positive 52-week Phase III results for both trials with dorzagliatin as monotherapy (HMM0301) and in combination with metformin (HMM0302), the Company plans to submit a new drug application (NDA) submission in China with the National Medical Products Administration (NMPA) for dorzagliatin as a Category 1 drug.

About Dorzagliatin

Dorzagliatin is a first-in-class glucokinase activator, or GKA, designed to control the progressive degenerative nature of diabetes by restoring glucose homeostasis in Type 2 diabetics. By addressing the defect of the glucose sensor function of glucokinase, or GK, dorzagliatin has the potential to repair the impaired glucose homeostasis state of Type 2 diabetics and serve as a first-line standard of care therapy for the treatment of Type 2 diabetes, or as a cornerstone therapy when taken in combination with currently approved anti-diabetes drugs.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that the Company will be able to develop, or ultimately market, dorzagliatin 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
Dr. Li Chen
*Chief Executive Officer and
Executive Director*

Hong Kong, August 30, 2019

As of the date of this announcement, the board of directors of the Company comprises Dr. Li Chen and Mr. George Chien Cheng Lin as executive directors of the Company; Mr. Robert Taylor Nelsen and Dr. Lian Yong Chen as non-executive directors of the Company; and Mr. Walter Teh-ming Kwauk, Mr. William Robert Keller, Mr. Junling Liu and Mr. Yiu Wa Alec Tsui as independent non-executive directors of the Company.