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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 MONOTHERAPY 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 monotherapy trial of dorzagliatin (HMS-5552), and therefore expects to release the topline results in the fourth quarter of 2019.

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 monotherapy trial targets drug naïve T2D patients, positioning dorzagliatin as first-line therapy. The monotherapy trial is a double-blind, placebo-controlled study and patients are randomized 2:1 for dorzagliatin or placebo. 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 40 clinical centres across China.

The Company expects to complete patient enrollment for its Phase III dorzagliatin combination with metformin trial in China (trial 302) by the middle of calendar year 2019, and to announce Phase III results for trial 302 in 1Q2020. Upon achieving positive Phase III results for both trials 301 and 302, the Company plans to submit a new drug application, or NDA, in China on a rolling basis with the CDA shortly thereafter for dorzagliatin as a Category 1 drug, and achieve China Drug Administration, or CDA, approval by the end of 2020 or early 2021.

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. The Company in-licensed the global rights to dorzagliatin from Roche. 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, March 1, 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.