HUA MEDICINE
華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(stock code: 2552)

BUSINESS UPDATE ON
FIRST PHASE III MONOTHERAPY TRIAL OF DORZAGLIATIN
ANNOUNCEMENT OF POTENTIAL INSIDE INFORMATION

This announcement is made by Hua Medicine (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Cap. 571) (the "**SFO**"). The information in this announcement may constitute inside information pursuant to the Inside Information Provisions under Part XIVA of the SFO.

The Company today announces 24-week top-line results from HMM0301 [NCT03173391], the first Phase III trial of a novel first-in-class dual-acting glucokinase (GK) activator, dorzagliatin (HMS5552), which was designed to restore glucose homeostasis through modulation of the glucose-sensor glucokinase in adults with type 2 diabetes. The Company is currently conducting two pivotal 52-week Phase III trials in China (dorzagliatin as a monotherapy and in combination with metformin), each with an initial 24-week double blinded, placebo-controlled treatment, followed by an open label 28-week treatment in which all patients receive dorzagliatin. In this HMM0301 trial, Chinese drug-naïve type 2 diabetes patients received 75 mg of dorzagliatin or placebo (randomized 2:1) twice per day and were monitored every four weeks during the first 24-weeks for efficacy and safety outcomes. The subsequent 28-week treatment period is ongoing.

The trial achieved its primary efficacy endpoint by demonstrating a statistically significant reduction in HbA1c levels over placebo during the first 24 weeks of the trial. Patients treated with dorzagliatin achieved 1.07 percent HbA1c reduction from baseline of 8.35 percent at 24 weeks compared to a reduction of 0.50 percent from a baseline of 8.37 percent in patients who received placebo (least square mean, p-value less than 0.0001). The American Diabetes Association (the "**ADA**") treatment target of HbA1c below 7.0 percent was achieved by 45.4 percent of subjects

on dorzagliatin (PPS data, p-value less than 0.0001), compared to 21.5 percent of subjects who received placebo. The homeostatic control rate, measured by the percentage of type 2 diabetes patients who achieved an HbA1c level of below 7.0 percent without hypoglycemia, reached 45.0 percent in subjects on dorzagliatin (PPS data, p-value less than 0.0001), and 21.5 percent in subjects on placebo.

Consistent with the findings from the Company's Phase II trial, which were published in *The Lancet Diabetes and Endocrinology* on May 4, 2018, dorzagliatin exhibited a safe and well-tolerated clinical profile during the 24-week period. Fewer than 1 percent of patients experienced clinically significant hypoglycemia[1] and no severe hypoglycemia[2] was reported, based on the ADA's guidelines. A safety analysis based on study safety population demonstrated that dorzagliatin was well tolerated and had a good safety profile. The incidence of adverse events was similar between the dorzagliatin-treated and placebo groups. The majority of the adverse events were mild in severity. No deaths and no drug-related serious adverse events were reported by investigators in the dorzagliatin-treated group.

The board of directors of the Company (the "**Board**") believes that the initial results indicate that dorzagliatin has the potential for the treatment of type 2 diabetes as it may be able to address the primary cause of type 2 diabetes by repairing glucose sensors and restoring glucose homeostasis through remodeling the endocrine functions of the pancreas, liver and intestine, which augment glucose homeostasis through regulation of insulin, glucagon and GLP-1 secretion. The Company has developed dorzagliatin to stop diabetes using a therapeutically minimum effective dose either as a cornerstone therapy to repair the glucose sensor function of glucokinase, or when necessary, in combination with widely prescribed diabetes medicines such as metformin, DPP-4, SGLT2, GLP-1 or insulin through a personalized type 2 diabetes care approach.

The Phase III trial HMM0302 [NCT03141073] targets patients who have failed metformin treatment and has recently completed enrollment. The Company is launching several clinical studies in the United States and China to investigate the effectiveness of dorzagliatin in different type 2 diabetes patient populations, and new indications in metabolic diseases and cognition. The Company is also evaluating dorzagliatin's efficacy in combination with other therapies in several additional ongoing clinical studies in China.

[1] Defined as less than 3.0 mmol/liter per the American Diabetes Association – *Standards of Medical Care in Diabetes – 2019.*

[2] Defined as hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery without regard to any specific glucose threshold, per the American Diabetes Association – *Standards of Medical Care in Diabetes – 2019*.

HMM0301 Study Design

HMM0301 [NCT03173391] is a randomized, double-blind, placebo-controlled Phase III study in 463 drug naïve type 2 diabetes patients. Patients are treated with twice-daily doses of dorzagliatin (75 mg) or placebo, randomized 2:1. The clinical study evaluates the efficacy and safety of dorzagliatin during 24 weeks of double-blinded treatment, followed by a subsequent 28-week open-label treatment period, for a total of 52 weeks. The trial was conducted in compliance with the guidelines of the Chinese Society of Endocrinology, which require physicians to educate patients and strictly enforce improved exercise and dietary control, as well as continuous self-monitoring, in treating type 2 diabetes. The primary efficacy endpoint is evaluated at the conclusion of the first 24 weeks. The trial is being conducted at 40 clinical sites across China led by Professor Dalong Zhu, President of the Chinese Diabetes Society. This is the first instance of a China-based biotech company achieving primary efficacy endpoint for a global first-in-class drug candidate in type 2 diabetes. The Company expects to release 52-week data in the second quarter of 2020.

About Dorzagliatin

Dorzagliatin is a first-in-class, dual-acting glucokinase activator, or GKA, designed to control the progressive degenerative nature of diabetes by restoring glucose homeostasis in people with type 2 diabetes. 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 people with type 2 diabetes and serve as a first-line standard of care therapy for the treatment of the disease, or as a cornerstone therapy when taken in combination with currently approved anti-diabetes drugs.

About the Company

The Company is a leading, clinical-stage innovative drug development company in China focused on developing novel therapies for the treatment of diabetes. Founded by an experienced group of entrepreneurs and international investment firms, the Company advanced a first-in-class oral drug for the treatment of type 2 diabetes into NDA-enabling stage and is currently evaluating the therapy in adults with diabetes in two Phase III trials in China and in two Phase I trials in the United States. The Company has also initiated product life-cycle management studies of this novel diabetes therapy and advanced its use in personalized diabetes care. The Company's strategy is to leverage the cost-efficient and high-quality drug development capabilities available in China, while working closely with disease experts and regulatory agencies in China and across the world to advance diabetes care solutions for patients worldwide.

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 release its 52 week data in the second quarter of 2020 or 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 the shares of the Company.

By Order of the Board
Dr. Li Chen
Chief Executive Officer and
Executive Director

Hong Kong, 11 November, 2019

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