HUA MEDICINE

華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(stock code: 2552)

BUSINESS UPDATE ON COMPLETION OF HMM0302, DORZAGLIATIN'S PHASE III METFORMIN COMBINATION TRIAL 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 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

On July 1, 2020, the Company announced that the pivotal Phase III registration trial evaluating Dorzagliatin (HMS5552) efficacy and safety in Type 2 diabetes patients inadequately glycemic controlled with metformin in China HMM0302, met the primary efficacy and safety end point in the double-blinded placebo-controlled and randomized 24-week trial. Statistically significant improvements in HbA1c response rate, HOMA2- β , HOMA2-IR, 2hPPG and FPG, were observed in the dorzagliatin-treated group over the placebo group.

Attached hereto as appendix 1 is the full text of the press release issued by the Company on July 1, 2020 China time, announcing the above described business updates.

Cautionary Statement required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on 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

Shanghai, July 1, 2020

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.

Hua Medicine Announces Positive 24-Week Topline Results of Phase III Metformin Combination Trial of Dorzagliatin

- *Met the primary efficacy and safety endpoints in the double-blinded placebo-controlled and randomized 24-week trial*

- *Dorzagliatin again demonstrated fast onset, potent and sustained HbA1c reduction of 1.02% from baseline at 24-week, and is superior over placebo treated group by 0.66% with a p-value less than 0.0001, in T2D patients whose blood glucose cannot be controlled with the maximum dose of metformin (1500mg/day).*

- *High response rate was observed in the treatment group with 44.4% of patients having achieved HbA1c level below 7% at 24-week*

- *Statistically significant improvements in HbA1c response rate, HOMA2- β and HOMA2-IR, 2hPPG and FPG, were observed in the dorzagliatin-treated group over the placebo group*

- *Clinically significant hypoglycemia incidence rate is less than 1% in the 24-week treatment period*

- *In the 24-week treatment period, dorzagliatin demonstrated a well-tolerated and good safety profile. There was no drug-related SAE, nor severe hypoglycemia reported*

July 1, 2020, Shanghai – Hua Medicine today announced the positive 24-week top-line results from HMM0302, a Phase III registration trial in China of its global first-in-class glucokinase activator dorzagliatin add-on to metformin, a first line oral antidiabetic therapy in Type 2 diabetes. All subjects are treated with metformin (Glucophage ®) at 1500mg/day as basic therapy throughout the entire 52-week treatment period. These patients are also given either twice-daily doses of dorzagliatin (75mg) or placebo, randomized on a 1:1 ratio. 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 when all patients will receive dorzagliatin 75mg twice daily. The primary efficacy endpoint is evaluated at the conclusion of the first 24 weeks. The subsequent 28-week treatment period is ongoing.

In 766 Type 2 diabetes patients whose blood glucose cannot be controlled with the maximum tolerated dose of equal or greater than 1500 mg/day of metformin, dorzagliatin demonstrated fast onset, potent and sustained HbA1c reduction of 1.02% (least squares mean) from baseline at 24-week, as compared to a reduction of 0.36% (least squares mean) from baseline for the placebo group (p-value less than 0.0001, 95% CI between -0.79 to -0.53).

The American Diabetes Association (ADA) treatment target of HbA1c below 7.0% was achieved by 44.4% of subjects on dorzagliatin and metformin, compared to 10.7% of subjects who received metformin only. Patients treated with dorzagliatin demonstrated statistically significant improvement of HOMA2- β , HOMA2-IR, 2hPPG and FPG over those in the placebo group.

In the 24-week period, dorzagliatin continued to exhibit a safe and well-tolerated clinical profile. There was less than 1% hypoglycemia with blood glucose < 3 mmol/L during the 24-week treatment period. There was no drug-related SAE, nor severe hypoglycemia reported.

"I am very pleased to see dorzagliatin provided very good glycemic control in the metformin-failed Type 2 diabetes patients in China," said Dr. Wenying Yang, a leading endocrinologist at the China-Japan Friendship Hospital and lead principal investigator of HMM0302 clinical study. "It offers a new solution to many patients whose blood glucose cannot be controlled with maximum tolerated dose of metformin, the first line therapy currently used for T2D treatment worldwide. I am very impressed by the determination and execution of Hua Medicine during the clinical trials, consistent with global standards, which leads to the high quality results in the 24-week period of HMM0302 trial."

"I am very excited to see the success in the HMM0302 clinical study. It will expand dorzagliatin into a very large patient population and help millions of T2D patients who failed in metformin treatment. It further supports our strategy to add dorzagliatin as a cornerstone therapy to current therapies including metformin, and DPP-IV inhibitors or SGLT-2 inhibitors, as well as GLP-1 and insulin. It will immediately expand our drug product pipeline based on the combination therapies," said Dr. Li Chen, CEO of Hua Medicine. "Through repairing the glucose sensor and improving the glucose sensitivity which addressed the underlying cause of T2D, dorzagliatin provides the synergy with existing antidiabetic medicines to better control diabetes. This is the first step to systematically address the heterogenic nature of T2D and provide a solution in personalized diabetes care."

Hua Medicine is planning to file an NDA in China after completing the second stage of the HMM0302 52-week study and developing one or more partnership to commercialize dorzagliatin in China and the rest of the world.

HMM0302 study design

HMM0302 Study is a randomized, double-blind, placebo-controlled Phase III study in 766 Type 2 diabetes patients inadequately glycemic controlled with metformin. Subjects are treated with metformin (Glucophage ®) at 1500mg/day as basic therapy throughout the whole 52-week treatment period. Patients are given twice-daily doses of dorzagliatin (75mg) or placebo, randomized on a 1:1 ratio. 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 receiving dorzagliatin 75mg twice daily. The primary efficacy endpoint is evaluated at the conclusion of the first 24 weeks. The trial is being conducted in 72 clinical sites across China led by Professor Wenying Yang at China-Japan Friendship Hospital. (NCT03141073).

About Dorzagliatin

Dorzagliatin is an investigational first-in-class, dual-acting glucokinase activator, designed to control the progressive degenerative nature of diabetes by restoring glucose homeostasis in patients with Type 2 diabetes. By addressing the defect of the glucose sensor function of glucokinase, dorzagliatin has the potential to restore the impaired glucose homeostasis state of patients 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 Hua Medicine

Hua 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, Hua 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 various earlier stage clinical trials in China and the United States. Dorzagliatin has achieved its first primary endpoint in a Phase III monotherapy trial. The Company has initiated product life-cycle management studies of this novel diabetes therapy and advanced its use in personalized diabetes care. Hua Medicine is working closely with disease experts and regulatory agencies in China and across the world to advance diabetes care solutions for patients worldwide.

For more information

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