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### **HUA MEDICINE**

# 華領醫藥

(Incorporated in the Cayman Islands with limited liability)
(stock code: 2552)

## VOLUNTARY ANNOUNCEMENT – UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS HUA MEDICINE ANNOUNCES ADDITIONAL DATA IN β-CELL FUNCTION

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 following findings from the DAWN study will be presented in oral and symposium presentations at the Chinese Diabetes Society's 2020 Scientific Meeting:

- Fast on-set of action (effective HbA1c reduction in 4 weeks)
- Significant improvement of  $\beta$ -cell function and reduction of insulin resistance in treatment group as compared to the placebo group
- Significant reduction of 2-hour post-prandial glucose reduction was observed in treatment group as compared to the placebo group
- Good safety profile and tolerance of dorzagliatin with limited hypoglycemia (Less than 1% observed during 24-week treatment)
- Sustained efficacy over 24 weeks
- Good response rate

Attached hereto as appendix 1 is the full text of the press release issued by the Company on November 26 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, November 26, 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's Dorzagliatin Announces Additional Data To Presented at the 2020 Chinese Diabetes Society Scientific Meeting

November 26, 2020 - Shanghai, China

Hua Medicine (the "Company", Stock Code: 2552.HK), a leading innovative drug development company focused on developing novel therapies for the treatment of diabetes, announced additional analysis results from dorzagliatin's 24-week metformin combination registration trial DAWN, (also known as HMM0302).

Findings from the DAWN study will be presented in oral and symposium presentations at the Chinese Diabetes Society's 2020 Scientific Meeting. The 24-week data indicates that, for Type 2 diabetes patients whose blood glucose cannot be controlled with the maximum tolerated dose of metformin (1,500mg/day), the dorzagliatin and metformin treatment group lowered HbA1c by 1.02%, superior over placebo treated group by 0.66% (placebo + metformin group reduced HbA1c by 0.36%). Dorzagliatin also demonstrated the below characteristics:

- Fast on-set of action (effective HbA1c reduction in 4 weeks)
- Significant improvement of  $\beta$ -cell function and reduction of insulin resistance in treatment group as compared to the placebo group
- Significant reduction of 2-hour post-prandial glucose reduction was observed in treatment group as compared to the placebo group
- Good safety profile and tolerance of dorzagliatin with limited hypoglycemia (Less than 1% observed during 24-week treatment)
- Sustained efficacy over 24 weeks
- Good response rate

"The analysis of dorzagliatin combination with metformin data continues to support the thesis of dorzagliatin in restoring glucose homeostasis," said Dr. Li Chen, CEO and CSO of Hua Medicine. "The results demonstrate dorzagliatin's potential in Type 2 diabetes patients who are metformin tolerant and continue to support our efforts to launch dorzagliatin in combination with other existing T2D drugs on the market to better serve the broad patient population."

In addition, dorzagliatin has demonstrated positive clinical results in combination studies with SGLT-2 and DPP-4 inhibitors, significantly enhancing glucose lowering effect.

#### In the trial, Dorzagliatin exhibits positive impact on blood glucose control.

The analysis of Phase III combination with metformin results show that dorzagliatin exhibits several promising characteristics for T2D treatment.

- Dorzagliatin combined with metformin treatment group achieved a statistically significant reduction of blood glucose 1.02% reduction in HbA1c from baseline, as compared to 0.36% in the metformin only group
- Dorzagliatin combined with metformin treatment group reached 40% response rate at week 8, and 44.4% at week 24
- Significant 2-hour post-prandial glucose reduction was observed (-5.45mmol/L vs -2.98mmol/L, p<0.0001)
- Patients saw fast on-set of blood glucose reduction during the first follow-up visit after initiation of treatment
- Hypoglycemia was very mild (less than 1% over 24-week period)
- Other incidences of adverse events were similar between the treatment and placebo groups
- Through HOMA2- $\beta^1$  analysis, the dorzagliatin treatment group demonstrated significant  $\beta$ -cell function improvement, with 3.77% increase in the treatment group, versus 1.35% in the placebo group.
- Note 1: The HOMA, Homeostatic Model Assessment, is a computer model to evaluate the beta cell function and insulin resistance in clinical studies that was developed in 1985. It is used to estimate the insulin sensitivity and beta cell function based on fasting glucose and insulin or c-peptide. HOMA2 is a computer model advance from HOMA1 and includes the factors of hepatic and peripheral insulin resistance, a physiological measure of glucose homeostasis.

Source: Diabetes Care 2004, 27(6), 1487

## **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. The Company has completed the Phase III monotherapy registration trial for dorzagliatin, and achieved the primary efficacy endpoint for a second Phase III registration trial for dorzagliatin combined with metformin, and expect to release 52-week data by year end 2020. Hua Medicine has received the drug manufacturing permit for dorzagliatin from the Shanghai Municipal Drug Administrative Bureau, and is preparing for NDA submission to the NMPA, in order to achieve dorzagliatin's "global first-in-class, launch in China first" goal, to benefit diabetes patients worldwide.

#### **About Hua Medicine**

Hua Medicine 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 Medicine advanced a first-in-class oral drug for the treatment of T2DM 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 primary endpoint in both of its Phase III monotherapy and combination trials in China over the 24-week trial period, and completed its 52-week 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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