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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 $\beta$ -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 Company is pleased to announce the post-analysis results from dorzagliatin’s 24-week monotherapy trial SEED (also known as HMM0301). The following findings were digitally presented in the oral and symposium presentations at the 80th Scientific Session of the American Diabetes Association.

- Fast on-set of action (effective HbA1c reduction in four weeks)
- Significant improvement of  $\beta$ -cell function in treatment group as compared to the placebo group
- Significant reduction of two-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 and similar incidence of adverse events between the treatment and placebo groups
- Sustained efficacy over 24 weeks
- Good response rate

## **Dorzagliatin showed improvements in marker that measures $\beta$ -cell function.**

Data demonstrates that there was significant  $\beta$ -cell function improvement (as measured by HOMA2- $\beta^1$ ) in the treatment group, with an increase of 2.56% in  $\beta$ -cell function recorded, as compared to the placebo group in which a decline of 0.72% in  $\beta$ -cell function was recorded.

## **In the trial, dorzagliatin exhibited positive impact on blood glucose control with a good safety profile.**

The post-analysis of Phase III monotherapy results show that dorzagliatin exhibited several positive characteristics for Type 2 Diabetes treatment.

- Dorzagliatin achieved a statistically significant reduction of blood glucose -1.07% reduction in HbA1c
- Two-hour post-prandial glucose reduction was observed (-2.83mmol/L vs -0.50mmol/L,  $p < 0.001$ )
- Patients saw fast on-set of blood glucose reduction during the first follow-up visit after initiation of treatment
- Hypoglycemia was very mild (one incidence out of 310 patients in the treatment group over the 24-week period)
- Other incidences of adverse events were similar between the treatment and placebo groups

“The post-analysis dorzagliatin data builds upon the positive results from our topline results,” said Dr. Li Chen, CEO and CSO of the Company. “The results demonstrate dorzagliatin’s potential to restore glucose homeostasis in Type 2 diabetes patients, and continue to support our efforts to launch dorzagliatin as a cornerstone therapy for the treatment of Type 2 Diabetes.”

In November 2019, the Company announced that the Phase III monotherapy trial (HMM0301) of dorzagliatin in drug naïve Type 2 Diabetes patients achieved its 24-week primary efficacy endpoint. The Company plans to announce the top-line 52-week key results for the monotherapy trial by no later than the third quarter of 2020. The 24-week patient visit for HMM0302, another Phase III combination trial of dorzagliatin add-on to metformin, was also completed. The Company plans to announce the top-line 24-week key results for the combination with metformin trial (HMM0302) by no later than the third quarter of 2020, and top-line 52-week key results by year-end 2020. In January 2020, the Company also announced the desirable results of dorzagliatin combination with sitagliptin Phase I trial (HMM0111), confirming the clinical advantages and potential synergies of dorzagliatin in combination with sitagliptin (a DPP-4 inhibitor). Meanwhile, the positive results of another Phase I trial (HMM0110) revealed the potential to use dorzagliatin in Type 2 Diabetes patients with late stage chronic kidney disease.

*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.

## **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.

**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, June 15, 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.*