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HUA MEDICINE

華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(stock code: 2552)

VOLUNTARY ANNOUNCEMENT

This announcement is made by Hua Medicine (the "**Company**" or "**Hua Medicine**") to provide its shareholders and potential investors with information in relation to the latest business update of the Company.

The Company today announced positive topline results from its U.S. Phase 1b multiple ascending dose (MAD) trial of HMS1005, a second-generation glucokinase activator (GKA). The trial was conducted in a group of adult patients (83% White) with Type 2 diabetes (T2D) in the United States. HMS1005 was generally well tolerated across multiple once-daily dose levels. Serum glucose measurements and continuous glucose monitoring (CGM) showed improvements in glucose control over the 14-day treatment period.

Dorzagliatin, the world's first GKA, launched in 2022. More than 10 million packs have been used in Mainland China to treat patients with Type 2 diabetes, or for the treatment of Type 2 diabetes. Dorzagliatin is designed to restore glucose homeostasis by improving glucose sensing, pancreatic secretory function, GLP-1 secretion, and hepatic glucose metabolism. This mechanism, together with the potential for disease modification and drug-free remission, informed the development of a second-generation, once-daily GKA for diabetes and other conditions associated with impaired glucose homeostasis and bioenergy deficiency.

HMS1005 is a second-generation glucokinase allosteric activator and a prodrug of dorzagliatin (HMS5552). Unlike dorzagliatin, which is taken twice daily, HMS1005 is designed for once-daily dosing. The Phase 1b study builds on Phase 1a pharmacokinetic findings, which showed efficient conversion of HMS1005 to dorzagliatin and prolonged systemic exposure.

The Phase 1b study evaluated the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of HMS1005 in patients with Type 2 diabetes. The study enrolled 48 patients across six cohorts and evaluated once-daily doses ranging from 123 mg to 492 mg. The safety, tolerability, and HMS5552 exposure findings support further evaluation of HMS1005 as a once-daily oral therapy for Type 2 diabetes and related metabolic diseases worldwide.

Key Results

- **Pharmacokinetics:** HMS1005 was efficiently converted to dorzagliatin (HMS5552) across all once-daily dose groups (123 to 492 mg). The once-daily extended-release formulation showed a favorable dose–exposure profile for dorzagliatin, based on peak concentration (Cmax) and area under the concentration–time curve (AUC), compared with findings from a prior MAD study of twice-daily dorzagliatin. These findings support further evaluation of HMS1005 in Phase 2 trials.

- **Safety and tolerability:** HMS1005 was generally safe and well tolerated at doses up to 492 mg once daily. No serious adverse events or episodes of severe hypoglycemia were reported, and no clinically meaningful hypoglycemia (blood glucose below 54 mg/dL or 3.0 mmol/L) was observed. Continuous glucose monitoring (CGM) showed no increase in time below range (TBR) at once-daily doses of 123 mg to 369 mg. 369 mg was identified as the maximum tolerated dose.

- **Glycemic control:** Continuous glucose monitoring showed improvements in glucose management indicator (GMI, an analogous measurement of blood glucose levels to HbA1c) and time in range (TIR). Across the drug tolerant once-daily dose groups from 123 mg to 369 mg, the TIR increased and GMI decreased with active parent drug HMS5552 exposure. The largest reduction in GMI was observed in the cohort with high impaired beta-cell function, where HMS1005 decreased the GMI by 1.48%, and increased the TIR from 35% to more than 80%, demonstrating glycemic control outcomes consistent with those observed in the clinical studies of dorzagliatin. The highest observed TIR increased from approximately 35% at baseline to more than 80% after treatment.

Advantage for once-daily prodrug PK profiles: The pharmacokinetic and pharmacodynamic findings support further evaluation of HMS1005 as a once-daily extended-release oral therapy. The prodrug HMS1005 and active parent drug HMS5552 exposure profiles support a waiver of long-term GLP toxicity study in the HMS1005 clinical development. If confirmed by the regulatory agency, once-daily dosing second-generation GKA development will be greatly accelerated.

Clinical Experience with Dorzagliatin

HMS1005 builds on Hua Medicine's experience with glucokinase activators. Dorzagliatin, marketed in mainland China as HuaTangNing (华堂宁®), has demonstrated glucose-lowering efficacy and a favorable safety profile in previous clinical studies and post marketing use. HuaTangNing (华堂宁®) has been prescribed to over 600,000 patients in mainland China.

At the 2026 American Diabetes Association Scientific Sessions, Hua Medicine presented findings on dorzagliatin from HMM0601, a multi-center post-marketing real-world study involving 2,024 patients with Type 2 diabetes across 80 clinical centers. During the 52-week observation period, no drug-related serious adverse events or episodes of severe hypoglycemia were reported, and the incidence of clinically meaningful hypoglycemia was below 1%. Patients also demonstrated improvements in HbA1c and glycemic control.

At the 2026 European Association for the Study of Diabetes Annual Meeting, further findings from HMM0601 showed that efficacy and safety of dorzagliatin in older adults (aged 65 years or older) and patients with reduced renal function were consistent with those observed in the overall study population.

Interim findings from HMM0701, a prospective real-world observational study, suggested that glucokinase activation may improve TIR and glucose homeostasis in patients with longstanding Type 2 diabetes.

A fixed-dose combination of dorzagliatin and metformin met its pivotal bioequivalence endpoints in recent clinical trials in mainland China. Hua Medicine expects to file a new drug application in 2027.

The clinical experience with dorzagliatin informs the development of HMS1005. Larger, longer trials are needed to establish the safety and efficacy of HMS1005 independently.

Next Steps

Hua Medicine plans to combine data from the Phase 1a and Phase 1b studies with existing clinical and nonclinical data for dorzagliatin to inform discussions with the U.S. Food and Drug Administration (FDA) on the HMS1005 development program. Future studies are expected to assess the efficacy and safety of selected once-daily doses over longer treatment periods, including effects on HbA1c and other measures of glycemic control.

Dr. Li Chen, Founder and CEO of Hua Medicine, said, "The Phase 1b results support further development of HMS1005, which builds on our experience with glucokinase activators."

"Drawing on our clinical experience with dorzagliatin, we will continue to evaluate whether HMS1005 can improve glucose control with once-daily dosing. We also plan to explore its potential in other indications, including diabetes prevention, prediabetes, and mild cognitive impairment."

Hua Medicine retains all global rights to HMS1005 and plans to engage with potential strategic and financial partners for development outside China.

About Type 2 Diabetes and Glucokinase

According to the International Diabetes Federation (IDF Diabetes Atlas, 11th edition), approximately 589 million adults worldwide are living with diabetes, a number projected to rise to 853 million by 2050. Type 2 diabetes accounts for the vast majority of cases. Despite the range of available therapies, many patients do not reach or maintain their blood glucose targets, as the disease progressively erodes the body's ability to sense and respond to changes in blood glucose.

Glucokinase (GK) serves as the body's glucose sensor. Found in the pancreas, liver and gut, it regulates glucose-stimulated insulin secretion, hepatic glucose uptake and storage, and the release of incretin hormones such as GLP-1. Impaired glucokinase function is a key defect in T2D. Glucokinase activators (GKAs) are designed to restore this sensing function, addressing an underlying cause of the disease rather than only lowering blood glucose. Hua Medicine's dorzagliatin, approved in China in 2022, is the world's first approved GKA.

About HMS1005

HMS1005 is an investigational new molecular entity and a prodrug of dorzagliatin. It has global patent protection extending to at least 2042. Hua Medicine is developing an extended-release formulation for once-daily oral dosing, with the goal of sustaining glucose control and potentially improving treatment adherence.

About Hua Medicine

Hua Medicine develops and commercializes drugs and is based in Shanghai, China, with subsidiaries in the United States and Hong Kong. Hua Medicine works with international partners to develop therapies for unmet medical needs, with a focus on diabetes. Hua Medicine's HuaTangNing (华堂宁®, dorzagliatin tablets) targets the glucose sensor glucokinase, restores glucose sensitivity in patients with Type 2 diabetes, and stabilizes imbalances in blood glucose levels in patients. HuaTangNing (华堂宁®) was approved by the National Medical Products Administration (NMPA) of China on September 30, 2022. It can be used alone or in combination with metformin for adult patients with Type 2 diabetes. For patients with chronic kidney disease, no dose adjustment is required. It is an oral glucose-lowering drug that can be used in T2D patients with renal function impairment.

In February 2026, dorzagliatin (trade name: MYHOMSIS®, 華領片®) was approved for marketing by the Pharmaceutical Service of the Department of Health of the Government of the Hong Kong Special Administrative Region of the People's Republic of China. In June 2026, dorzagliatin (trade name: MYHOMSIS®, 華領片®) was approved for marketing by the Pharmaceutical Administration Bureau of the Government of the Macao Special Administrative Region of the People's Republic of China. Based on the International Diabetes Federation's 2025 Diabetes Atlas – 11th Edition, there were approximately 148 million diabetic patients in mainland China, 706,000 diabetic patients in Hong Kong SAR, and 52,000 diabetic patients in Macao SAR as of 2024.

Cautionary Statement required by Rule 18A.08(3) of the Listing Rules: The Company cannot guarantee that HMS1005 will ultimately be successfully developed and marketed. Shareholders and potential investors of the Company are advised to exercise due caution when dealing in the shares of the Company.

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

Shanghai, 23 November 2026

As of the date of this announcement, the Board comprises Dr. Li Chen, Mr. George Chien Cheng Lin and Dr. Yi Zhang as executive Directors; Mr. Robert Taylor Nelsen as non-executive Director; and Mr. William Robert Keller, Mr. Yiu Wa Alec Tsui and Mr. Yiu Leung Andy Cheung as independent non-executive Directors.