HUA MEDICINE
華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(stock code: 2552)

BUSINESS UPDATE
APPROVAL OF NDA OF HUATANGNING (華堂寧®), INNOVATIVE FIRST-IN-CLASS GKA POTENTIAL INSIDE INFORMATION

This announcement is made by Hua Medicine (the "**Company**" or "**Hua Medicine**") 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).

The Company is pleased to announce that on October 9, 2022, the New Drug Application (NDA) of HuaTangNing (華堂寧®) (dorzagliatin tablets, HMS5552), a first-in-class glucokinase activator (GKA) developed by the Company, has been officially approved by the National Medical Products Administration (NMPA) of China on October 8th, to be used as monotherapy for drug naïve Type 2 diabetes (T2D) patients or in combination with metformin in metformin tolerated T2D patients to control blood glucose level. For those patients with chronic kidney disease (CKD) and Type 2 diabetes (i.e., diabetes kidney disease), no dose adjustment is required.

HuaTangNing (華堂寧®) is the first approved glucokinase activator (GKA) worldwide. It represents a new mechanism of action introduced in global diabetes treatment since the last decade, and the first time in history that a global first-in-class drug for Type 2 diabetes is introduced first in China. With the approval of HuaTangNing (華堂寧®), Hua Medicine will transition from pure R&D focus to commercialization stage. Going forward, Hua Medicine will partner with Bayer, a leading global pharmaceutical company, to commercialize HuaTangNing (華堂寧®) in China, benefiting more diabetic patients and their families.

Attached hereto as Appendix 1 is the full text of the press release issued by the Company on October, 9, 2022 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 it 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, October, 9, 2022

As at 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 Ms. Wei Zhao 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.

Appendix 1

Hua Medicine's Innovative First-In-Class Glucokinase Activator (GKA) HuaTangNing (華堂寧®) Is Approved! New Type 2 Diabetes Treatment Paradigm to Begin in China

October, 9, 2022 – China, Shanghai

Hua Medicine (the "Company", HKEx Stock Code: 2552.HK) today announces that the New Drug Application (NDA) of HuaTangNing (華堂寧®) (dorzagliatin tablets, HMS5552), a first-in-class glucokinase activator (GKA) developed by the Company has been approved by the National Medical Products Administration (NMPA) of China on October 8th for two indications, both to improve blood glucose control for Type 2 diabetes (T2D) patients, as monotherapy for drug naïve T2D diabetes patients or in combination with metformin in metformin tolerated T2D patients to control blood glucose level. For those patients with chronic kidney disease (CKD) and Type 2 diabetes (i.e., diabetes kidney disease), no dose adjustment is required. At the same time, clinical trials have shown that HuaTangNing (華堂寧®) in combination with empagliflozin (SGLT-2 inhibitor) and sitagliptin (DPP-IV inhibitor) is expected to better improve blood glucose control and pancreatic islet functions in T2D patients than either empagliflozin or sitagliptin taken alone.

HuaTangNing (華堂寧®) is the first approved glucokinase activator (GKA) worldwide. Accordingly, the commercialization of HuaTangNing (華堂寧®) represents the first time globally in almost ten years that a new mechanism of action to treat Type 2 diabetes is introduced, and the first time in history that a global first-in-class drug for Type 2 diabetes is introduced first in China. This milestone represents unprecedented progress in the application of innovative scientific concepts in the Chinese biopharmaceutical industry to meet the clinical needs of Chinese patients. HuaTangNing (華堂寧®) is the first innovative first-in-class drug developed using the operation model of "Integration of global pharmaceutical research and development resources, to achieve joint innovation," and whereby China has led pharmaceutical innovation into a new historical stage.

With the mission of "For Patients, Global Innovation, Effective Medicines", Hua Medicine has independently developed HuaTangNing (華堂寧®), a first-in-class drug based on the characteristics of Chinese diabetic patients. Since the beginning of its scientific development, the research and development project of HuaTangNing (華堂寧®) has been highly valued by the new drug R&D community and national drug regulators. The project was selected as a national key scientific and technological project during the "12th Five-Year Plan" and the "13th Five-Year Plan" periods. HuaTangNing (華堂寧®) is a drug with new concept, new mechanism, new efficacy, new structure and new technology. It is led by a Chinese R&D team and Chinese clinical researchers from pre-clinical to Phase I, II, and III clinical trials. Therefore, it is not only a major R&D breakthrough in translating innovative concepts into innovative products, but also a pioneering path for China in developing first-in-class drugs independently. The approval of HuaTangNing (華堂寧®) also represents the first approved GKA drug, after many large and small pharmaceutical companies globally have spent over 2 decades of R&D resources on the glucokinase activator class, thereby achieving a breakthrough from zero. Going forward, Hua Medicine will partner with Bayer, a leading global pharmaceutical company, to commercialize HuaTangNing (華堂寧®) in China, benefiting diabetic patients and their families.

Globally, the incidence of diabetes has been on the rise. According to the International Diabetes Federation (IDF), the number of adult diabetes patients worldwide reached 537 million in 2021, which was an increase of 74 million or 16% from 2019. Global health spending due to diabetes and its complications stood at USD966 billion in 2021. China is no exception. There were over 140 million diabetic patients in 2021, 51.7% of which (around 72.83 million) have not been diagnosed or treated. In addition, fluctuating blood glucose levels lead to a series of diabetic complications such as cardiovascular and cerebrovascular, kidney, eye diseases, and diabetic feet, etc., which greatly affect the survival and life quality of diabetic patients, and exert a heavy pressure on their families. Therefore, stabilizing the T2D patient's blood glucose level at a good TIR (Time in Range) is an important goal in diabetes treatment and management. According to the 14th Five-Year National Health Planning issued by the General Office of the State Council, improving the prevention and treatment capacity of diabetes and other major chronic diseases is a key health-care topic for the country. It is estimated that over 65% of T2D patients will be covered by the health management service of community-level medical institutions during the 14th Five Year Plan period. The NDA approval and HuaTangNing (華堂寧®) adheres closely to the national strategy of developing the pharmaceutical industry and improving citizens' health.

A rapidly growing population of diabetic patients and a huge market for diabetes drugs clearly establish strong unmet medical needs. With the original concept of "repairing the sensor, restoring homeostasis, and treating the underlying cause of diabetes", Hua Medicine boldly aims at directly addressing the root cause of the failure of blood glucose sensors in T2D patients. Clinical studies have shown that HuaTangNing (華堂寧®) can restore the impaired glucokinase sensor function and improve the ability of T2D patients to regulate blood glucose autonomously, thus potentially control the progression and complications of Type 2 diabetes from its source.

As a new class of T2D treatment drug, the R&D of HuaTangNing (華堂寧®) has received continuous attention from the academic community worldwide. In 2018, the results of its Phase II clinical trial were published in *The Lancet Diabetes and Endocrinology*, a top international medical journal, which was the first time for the journal to publish the clinical research results of a T2D original innovative drug from China. In May 2022, *Nature Medicine*, a top international medical journal, simultaneously published two peer-reviewed papers on the results of our two Phase III clinical trials, describing the results of our monotherapy trial (the SEED study), and in combination with metformin trial (the DAWN study), respectively. It fully recognized HuaTangNing (華堂寧®) as a first-in-class diabetic drug with significant safety advantages and the characteristics of improving pancreatic islet functions in T2D patients. The unique advantages of HuaTangNing (華堂寧®) in T2D patients with nephropathy suggested by the clinical trials was also highlighted.

Other clinical research also showed that HuaTangNing (華堂寧®) safely creates clear synergies in combination therapy with DPP-4 inhibitors and SGLT-2 inhibitors in blood glucose control, suggesting its broader potential in T2D patients with different needs in glycemic control and at different stages of disease progression. By potentially restoring early-phase insulin secretion and improving β-cell function, HuaTangNing (華堂寧®) is expected to be a key path in diabetes remission. In the future, Hua Medicine will continue to explore HuaTangNing (華堂寧®)'s potential in the remission of T2D drug discontinuation and the combination therapies with the other nine existing types of diabetes drugs. Hua Medicine is committed to addressing the needs of diabetic prevention, remission and complication control, and bringing Chinese innovation to the world.

Xiaolan Zhou, Executive Vice President, Pharmaceuticals Division, Bayer AG and President of Bayer Pharmaceuticals China, said, "Bayer has been working on diabetes treatment and contributing to the development of diabetes prevention and treatment in China for years. HuaTangNing (華堂寧®) and Glucobay®, the first oral hypoglycemic drug with impaired glucose tolerance (IGT), together with continuous glucose monitoring systems (CGMs), establish end-to-end course management from prevention to treatment for Chinese T2D patients. Real-time blood glucose monitoring helps achieve the goal of 'steady blood glucose control'. At the same time, Bayer proactively explores digital solutions to help hundreds of millions of Chinese patients to achieve the vision of diabetes-free."

Dr. Li Chen, the founder, CEO and Chief Scientific Officer of Hua Medicine, said, "the NDA approval of HuaTangNing (華堂寧®) is a major milestone for Hua Medicine, as it also marks that the innovative drug industry in China has entered a new stage of new development. Diabetes chronic disease management is strategically important for China's economy and people's livelihood. Hua Medicine adheres to our original intention of 'China leading pharmaceutical innovation'. Amid fierce international competition, researchers and partners of Hua Medicine have spent 10 years of hard work to develop the first-in-class new diabetes drug – first in the world and start from China, achieving a breakthrough from zero. This achievement is attributed to all Chinese scientists, clinicians and partners participated in the R&D of HuaTangNing (華堂寧®). We are proud of HuaTangNing (華堂寧®) and grateful to everyone for their hard work and wholehearted dedication. At the same time, Hua Medicine looks forward to in-depth integration and full vitality with Bayer in the commercialization of HuaTangNing (華堂寧®), which will bring new hope of diabetes prevention, treatment and relief to up to one hundred million Chinese T2D patients, establish standards for diabetes prevention and treatment, and contribute to the national strategy of achieving Healthy China 2030."

About HuaTangNing (華堂寧®)

HuaTangNing (華堂寧®) (dorzagliatin tablets) is a first-in-class glucokinase allosteric activator (GKA) with a brand-new mechanism. It can be used alone or in combination with metformin hydrochloride (when using metformin hydrochloride alone is ineffective in controlling blood glucose), to improve blood glucose control for T2D adult patients with diet and exercise. HuaTangNing (華堂寧®) targets at restoring the impaired glucose sensor glucokinase (GK) in pancreas, intestine and liver, to achieve one target with multiple points and coordinated blood glucose control. It regulates glucose stimulated secretion of the glycemic controlling hormones insulin, GLP-1 and glucagon in diabetes patients, which leads to the improvement of early-phase insulin secretion and disposition index. It has potential in restoring glucose homeostasis and diabetes remission. Results from two Phase III registered trials of HuaTangNing (華堂寧®) monotherapy and combination therapy with metformin in metformin tolerated T2D patients have shown that HuaTangNing (華堂寧®) significantly improves glycemic control with effective reduction of post prandial glucose, low risk of hypoglycemia, well tolerance and safety. HuaTangNing (華堂寧®) demonstrated a linear correlation between drug dose and plasma exposure, with high target organs distributed in pancreas, intestine and liver. It showed low renal excretion and similar pharmacokinetic profiles at End Stage Renal Disease (ESRD) patients and healthy subjects, which suggest it can be readily used in those patients with renal insufficiency without dose adjustment. The unique mechanism of action, desirable pharmacokinetic, and good safety and tolerability profile establish HuaTangNing (華堂寧®) as a differentiated new class of anti-diabetes therapy.

About Hua Medicine

Hua Medicine is an innovative drug development company found in China, focused on developing novel therapies for patients worldwide with unmet medical needs. Based on global resources, Hua Medicine teams up with global high-caliber people to develop breakthrough technologies and products, which contribute a global innovation in diabetes care. Targeting the glucose sensor, glucokinase, HuaTangNing (華堂寧®) (dorzagliatin tablets) as Hua Medicine's cornerstone product, restores glucose sensitivity in T2D patients and has completed registered SEED and DAWN Phase III trials in China. The NDA (New Drug Application) of HuaTangNing (華堂寧®) has been officially approved by the China National Medical Products Administration (NMPA). This first-in-class glucokinase activator has demonstrated its potential of achieving diabetes remission to help millions of diabetic patients around the world.

About Bayer

Bayer is a global enterprise with core competencies in health and agriculture of life science. Its products and services are designed to help human and the earth thrive by supporting the efforts to overcome major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable growth and having a positive impact on business. At the same time, Bayer aims to increase its profitability and create value through innovation and growth. Globally, the brand of Bayer stands for trust, reliability and quality. In the fiscal year of 2020, Bayer had around 100,000 employees, 41.4 billion euros of sales, and 4.9 billion euros of R&D expenses (excluding special programs). For more information, please visit www.bayer.com.

About the cooperation between Hua Medicine and Bayer

In August 2020, Bayer, a multinational pharmaceutical company, and Hua Medicine, a Chinese innovative drug research and development company, announced a strategic partnership on dorzagliatin, a first-in-class diabetes treatment drug, in China. This partnership aims at leveraging Bayer's prominent advantages in diabetes management in China and Hua Medicine's R&D expertise in diabetes treatment. Both parties are committed to benefiting hundreds of millions of China diabetic patients through new therapeutic options. Under the terms of the agreement, Hua Medicine as the market authorization holder (MAH) shall be responsible for clinical development, registration, product supply and distribution, while Bayer as the promotion service provider shall be responsible for marketing, promotion and medical education activities in China. The Pharmaceuticals China Innovation Center of Bayer facilitated this collaboration. As a global pharmaceutical leader, Bayer is committed to cooperating with external partners to promote breakthrough innovations, bring positive changes to patients, and achieve the goal of "cooperative innovation and joint cure".