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#### **HUA MEDICINE**

### 華領醫藥

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

# BUSINESS UPDATE ON COMMERCIALIZATION AGREEMENT AND STRATEGIC PARTNERSHIP FOR INVESTIGATIONAL FIRST-IN-CLASS NOVEL DIABETES TREATMENT DORZAGLIATIN WITH BAYER IN CHINA 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).

The board of directors of the Company (the "Board") is pleased to announce that, on August 17, 2020, Hua Medicine (Shanghai) Ltd ("Hua Shanghai"), a wholly-owned subsidiary of the Company, entered into a strategic collaboration agreement (the "Agreement") with Bayer Healthcare Company Limited ("Bayer") to commercialize and form a strategic partnership for dorzagliatin, a novel diabetes treatment, in China.

The commercialization agreement and strategic partnership aims to provide Chinese diabetes patients with access to a new treatment option, building on Bayer's existing strength and leadership in diabetes management in China and the innovation capabilities of the Company.

Under the terms of the agreement, the Company as the market authorization holder shall be responsible for clinical development, registration, product supply and distribution, whilst Bayer as the promotion service provider shall be responsible for marketing, promotion and medical education activities in China. The Company will receive an upfront payment of RMB300 million and additional payments could reach up to RMB4.18 billion if certain milestones are met. Bayer receives the exclusive rights to commercialize the product in China and will receive tiered service fee based on the net sales. Initially, both parties will share equally in sales derived from China net sales, with adjusting sales percentages based on agreed China net sales thresholds.

Attached hereto as appendix 1 is the full text of the press release issued by the Company on August 17, 2020 China time, announcing the above business update.

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, August 17, 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.

#### Appendix 1

## Bayer and Hua Medicine announce commercialization agreement and strategic partnership for investigational first-in-class novel diabetes treatment dorzagliatin in China

- Investigational first-in-class glucokinase activator, with a novel mode of action, focused on fixing the glucose sensor and restoring glucose homeostasis for Type 2 diabetes mellitus ("T2DM") patients, with sustained efficacy in phase III clinical trial in Chinese T2DM patients.
- 116 million T2DM patients in China, with an unsatisfied treatment and control rate.
- Agreement further strengthens Bayer's diabetes management leadership in China.

Beijing and Shanghai, China, August 17, 2020 – Bayer and Hua Medicine, a leading innovative drug development company, today announced a commercialization agreement and strategic partnership for dorzagliatin, a novel diabetes treatment, in China. The agreement aims to provide Chinese diabetes patients with access to a new treatment option, building on Bayer's existing strength and leadership in diabetes management in China and the innovation capabilities of Hua Medicine.

"Bayer has been long committed to Chinese patients living with diabetes and diabetic macular edema (DME) by offering innovative treatment options including Glucobay® and Eylea®," said Wei Jiang, Executive Vice President and President of Bayer Pharmaceuticals Region China & APAC and President of Bayer Group Greater China. "In the face of significantly increasing challenges caused by diabetes to public health in China, our collaboration with Hua Medicine will further address unmet medical needs of Chinese patients living with diabetes. By leveraging Bayer's well-established products as well as the upcoming continuous glucose monitoring system under the partnership with WaveForm, we will be able to provide integrated solutions ranging from prevention, diagnosis, treatment and complication management."

Type 2 diabetes continues to be an important health challenge. According to the China Mainland National Cross Sectional Study in the British Medical Journal, the prevalence rate of T2DM for adults in China is 11.2%, but the proportion of patients who have their hemoglobin A1c (HbA1c) levels controlled is 49.4%. Among patients taking oral anti-diabetic drugs, fasting plasma glucose and 2-hour postprandial plasma glucose level lower than or equal to target were only achieved by 51.3% and 53.4%, respectively. These observations from real-world data highlights the unmet medical needs in diabetes, and are the reasons why biotech companies continue to explore novel therapies to improve diabetes management. With a novel mechanism of action, dorzagliatin is an investigational first-in-class glucokinase activator ("GKA") targeting the restoration of glucose homeostasis in T2DM patients by addressing the defect of the glucose sensor function in the pancreas. A recently completed phase III clinical study of dorzagliatin monotherapy by Hua Medicine showed positive 52-week efficacy data. In addition, 24-week topline results were announced recently: The phase III metformin combination clinical trial met the primary efficacy endpoint.

British Medical Journal. Prevalence of diabetes recorded in China using 2018 diagnostic criteria from the American Diabetes Association: national cross sectional study. https://www.bmj.com/content/369/bmj.m997

"We are very excited to have this great opportunity, joining forces with Bayer to bring a first-in-class diabetes medicine, dorzagliatin, to Chinese patients," said Dr. Li Chen, CEO of Hua Medicine. "Bayer has been a leader in diabetes treatment for the past 10 years in China and will be a great partner for Hua Medicine to advance diabetes care. T2DM currently affects approximately 463 million patients worldwide, 116 million of which are in China.<sup>2</sup> Over the last ten years, Hua Medicine has translated the novel concept of glucose homeostasis management into a breakthrough T2DM therapy that aspires to cure diabetes. For the first time, a drug has demonstrated, in clinical trials, the potential ability to improve glucose metabolism and  $\beta$ -cell function in T2DM patients. The partnership between Hua Medicine and Bayer will bring this medical innovation to a broader patient population in China even faster."

Under the terms of the agreement, Hua Medicine as the market authorization holder shall be responsible for clinical development, registration, product supply and distribution, whilst Bayer as the promotion service provider shall be responsible for marketing, promotion and medical education activities in China. Hua Medicine will receive an upfront payment of RMB300 million and additional payments could reach up to RMB4.18 billion if certain milestones are met. Bayer receives the exclusive rights to commercialize the product in China and will receive tiered service fee based on the net sales. Initially, both parties will share equally in sales derived from China net sales, with adjusting sales percentages based on agreed China net sales thresholds.

"China is a key focus of Bayer's partnering efforts and we are continuously looking for assets and health technologies to help address significant unmet medical needs of patients," said Marianne De Backer, PhD, Member of the Executive Committee and Head of Strategy and Business Development & Licensing, Pharmaceuticals Division of Bayer AG. "Through this new partnership, we further expand treatment options for millions of Type 2 diabetes patients in China by leveraging our commercial expertise and diabetes leadership position in China and combining it with the external know-how of a strong partner."

The Pharmaceuticals Business Development & Licensing team of Bayer facilitated this collaboration.

#### **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 T2DM. 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 T2DM and serve as a standard-of-care therapy for the treatment of the disease, or as a combination therapy with currently approved anti-diabetes drugs. For more information, please go to www.huamedicine.com.

International Diabetes Federation. 9th Edition of IDF Diabetes Atlas. https://www.diabetesatlas.org/en/

#### **About Bayer**

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

#### **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 to satisfy unmet medical needs. 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.

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#### **Bayer Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at <a href="www.bayer.com">www.bayer.com</a>. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

#### **Hua Forward-Looking Statements**

This press release may contain statements that constitute "forward-looking statements", including, but not limited to, statements relating to the implementation of strategic initiatives, and other statements relating to Hua Medicine's future business development and economic performance. While these forward-looking statements represent Hua Medicine's judgments and future expectations concerning the development of business, a number of risks, uncertainties and other statutory requirements may render actual developments and results to differ materially from our expectations. For more information, go to www.huamedicine.com.