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# SHENZHEN HEPALINK PHARMACEUTICAL GROUP CO., LTD. (深圳市海普瑞藥業集團股份有限公司)

(A joint stock company incorporated in the People's Republic of China with limited liability) (Stock Code: 9989)

# ANNOUNCEMENT ON PASSING OF CONSISTENCY EVALUATION FOR THE GENERIC DRUG OF ALL STRENGTHS OF "ENOXAPARIN SODIUM INJECTION"

This announcement is made by Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (the "**Company**", together with its subsidiaries referred to as the "**Group**") pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Rules Governing the Listing of Stocks on Shenzhen Stock Exchange.

The board of directors of the Company (the "**Board**") is pleased to announce that Shenzhen Techdow Pharmaceutical Co., Ltd. ("**Shenzhen Techdow**"), a wholly-owned subsidiary of the Company, has recently received the Notice of Approval of Supplementary Drug Application (the "**Notice**") issued by the National Medical Products Administration ("**NMPA**"), where Shenzhen Techdow's enoxaparin sodium injection of all five strengths sold domestically has passed the consistency evaluation of quality and efficacy of generic drugs (the "**QCE**").

#### **DETAILS OF THE DRUG**

- (I) Drug name: Enoxaparin Sodium Injection
- (II) Indications: Prophylaxis of venous thromboembolic disease (prophylaxis of venous thrombosis), especially thrombosis related to orthopedics or general surgery; treatment of developed deep vein thrombosis with or without pulmonary embolism, or pulmonary embolism with light clinical syndromes, excluding pulmonary embolism requiring surgeries or thrombolytic therapies; treatment of unstable angina and non-Q-wave myocardial infarction in combination with aspirin; and used in hemodialysis and extracorporeal circulation to prevent thrombosis

- (III) Strength: 20mg/0.2mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/1.0mL
- (IV) Registration category: Chemical medicine
- (V) Original drug approval number: Guo Yao Zhun Zi H20056846, Guo Yao Zhun Zi H20056847, Guo Yao Zhun Zi H20056848, Guo Yao Zhun Zi H20056849 and Guo Yao Zhun Zi H20056850
- (VI) Review and approval conclusion: Upon review, the drug passed the consistency evaluation of quality and efficacy of generic drugs, and the changes to quality standards have been approved. The quality standards and manufacturing processes shall be implemented according to the Notice. The validity period is 36 months.

## **OTHER RELATED INFORMATION**

Studies have shown that enoxaparin finished dose is able to treat various diseases in the areas of cardiology, nephrology and neurology. Compared to novel oral anticoagulants (NOACs), enoxaparin finished dose has wider applications and can be used for treatments of diseases in which the use of NOACs has not been approved. For example, enoxaparin finished dose can be used to treat acute ST-segment elevation myocardial infarction and prevent thrombosis in blood dialysis, and for prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction. The wide application and continuous expansion of the indications of enoxaparin finished dose demonstrate significant growth potential of the global enoxaparin market.

The U.S. and Europe are the major markets for finished dose enoxaparin sodium pharmaceutical products, and the enoxaparin finished doses market in China has grown rapidly in the recent years. According to the Frost & Sullivan report, the sales of finished dose enoxaparin sodium pharmaceutical products in China has increased from US\$103 million in 2014 to US\$308 million in 2019, at a CAGR of 24.5%. China market has significant growth potential. Compared with Europe and the U.S., in which the penetration rate of enoxaparin finished dose is relatively high, the usage per capita of enoxaparin finished dose in emerging markets, such as China, is much lower. The per capita usage of enoxaparin in the European Union was 0.95 syringe in 2018, while the per capita usage remained relatively low in China, reaching 0.03 syringe in 2018. With more generic drugs being marketed and the increasing awareness of the importance of anticoagulation in patients and doctors, the penetration rate of enoxaparin finished dose will keep increasing in emerging markets, especially in China. The usage of enoxaparin in China was 52 million syringe/vial in 2019, which is expected to increase at a CAGR of 23.6% to 186 million syringe/vial in 2025. Total sales of enoxaparin in China reached US\$308 million in 2019, and is expected to reach US\$698 million in 2025.

Shenzhen Techdow's enoxaparin sodium finished dose products of all five strengths have been approved in a total of 35 countries and sold in 21 countries. In addition, Shenzhen Techdow also can supply enoxaparin sodium injection to its customers in 15 other countries, including the United States. In the first half of 2020, the Company's global sales volume of enoxaparin finished dose reached RMB640 million, representing a year-on-year increase of 37%.

## **BENEFITS AND IMPACTS TO THE COMPANY**

According to the Opinion on Conducting the Consistency Evaluation of the Quality and Efficacy of Generic Drugs (No. 8 [2016] of the State Council's Office), for the drug varieties passing the QCE of generic drugs, medical institutions should give priority to procurement and clinical application, and if more than three manufacturing enterprises of the same variety of drug have passed the QCE, varieties that have not passed the QCE will no longer be selected in course of centralized drug procurement.

Shenzhen Techdow is the first domestic enterprise to apply for and pass the QCE of the generic enoxaparin sodium injection of all five strengths, and the product strengths covered are also the most comprehensive among the companies that have applied for the QCE of this variety. Currently, the finished dose enoxaparin sodium pharmaceutical products of Shenzhen Techdow are mainly exported to the European Union, and the domestic sale accounts for a relatively low rate of the revenue from the business of finished dose enoxaparin sodium pharmaceutical products on the whole. All the five strengths of enoxaparin sodium injection of Shenzhen Techdow's competitiveness in the domestic market and help Shenzhen Techdow to seize opportunities in the new market environment where provincial centralized drug procurement is continuously promoted, and it is expected to have a positive impact on the Company's future operating results.

By order of the Board Shenzhen Hepalink Pharmaceutical Group Co., Ltd. Li Li Chairman

Shenzhen, PRC October 26, 2020

As at the date of this announcement, the executive directors of the Company are Mr. Li Li, Ms. Li Tan, Mr. Shan Yu and Mr. Sun Xuan; the non-executive director of the Company is Mr. Bu Haihua; and the independent non-executive directors of the Company are Dr. Lu Chuan, Mr. Chen Junfa and Mr. Wang Zhaohui.