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**Hepalink**

**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)**

## **ENOXAPARIN SODIUM INJECTION OBTAINS APPROVAL FROM FDA**

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. (“**Shen hen Techdo**”), a wholly-owned subsidiary of the Company, has been notified that, the U.S. Food and Drug Administration (“**FDA**”) had approved its registration as a supplier of the finish dose medicines and active pharmaceutical ingredients to the license holder for enoxaparin sodium injection (such holder should have extensive channels and experiences in generic pharmaceutical industry, and generated over US\$10 billion in revenue in 2019).

### **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 embolism 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) Dosage form: Injection
- (IV) Strength: 100 mg/mL (30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL); 150 mg/mL (120mg/0.8mL)

(V) Registration category: Generic drug

(VI) Supplementary approval content: Addition of the supplier of drugs and active pharmaceutical ingredients under the original marketing approval, namely Shenzhen Techdow

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

Currently, Inhixa, Neoparin and Prolongin, the three enoxaparin sodium injection brands of the Group, have been approved in a total of 35 countries and sold in 21 countries. Meanwhile, the Group also can supply enoxaparin sodium injection to its customers in 15 other countries, including the United States. This approval is also the first time that Shenzhen Techdow's DMF (Drug Master File) for enoxaparin sodium active pharmaceutical ingredients has been approved by the FDA for activation in the United States.

The United States is a major and growing market for the sales of enoxaparin sodium injections. According to the Frost & Sullivan report, the sales of finished dose enoxaparin sodium pharmaceutical products in the United States amounted to approximately US\$455 million in 2019, accounting for approximately 17% of the global market sales. The United States market is expected to grow at a CAGR of 10.7% to reach US\$838 million in 2025.

In the first half of 2020, the Group's global sales of enoxaparin sodium injection was increased by 37%, with unaudited sales revenue of RMB631.3 million. The Group is currently the sole supplier of enoxaparin sodium injection to the strategic partner that holds the marketing license in the United States; and the partner is responsible for all sales and distribution related expenses. The approval of this registration marks the beginning for the Group's finished dose pharmaceutical products entering the market in the United States. The Group expects to achieve sales by the end of this year. The future growth of finished dose pharmaceutical products business in the United States will further consolidate the Group's global business layout.

Announcement is hereby given.

By order of the Board  
**Shen hen Hepalink Pharmaceutical Group Co., Ltd.**  
**Li Li**  
*Chairman*

Shenzhen, PRC  
September 21, 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.*