



**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)**

**VOLUNTARY ANNOUNCEMENT**

**ENOXAPARIN SODIUM INJECTION. OBTAINED ANDA  
APPROVAL FROM FDA**

This announcement is made by Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (the “**Compan** ” or “**Hepalink**”, together with its subsidiaries referred to as the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

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 the abbreviated new drug application (“**ANDA**”) for its enoxaparin sodium injection.

**DETAILS OF THE DRUG**

- (I) Drug name: Enoxaparin Sodium Injection USP
- (II) Indications: Prophylaxis and treatment of deep venous thromboembolism, for example the prophylaxis and treatment of deep venous thrombosis such as abdominal surgery, hip replacement surgery and knee replacement surgery; and also prophylaxis of unstable angina and non-Q wave myocardial infarction, and treatment of acute ST segment elevation myocardial infarction
- (III) Dosage form: Injection

(IV) Strength: 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/1mL, 120mg/0.8mL, 150 mg/1mL

(V) Registration category: Generic drug

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

According to IQVIA, the United States is the second largest consumer market for enoxaparin sodium finished doses in the world after Europe, with sales of approximately 100 million units of enoxaparin sodium finished doses in 2022, accounting for approximately 13% of that of the global market. Hepalink has always attached great importance to the United States market and has entered the United States market through its partner after obtaining approval from the United States FDA to supply drugs to the license holder for enoxaparin sodium finished doses in September 2020 for the sale of the Group's enoxaparin sodium finished doses. In the past two years, the sales of the Group's enoxaparin sodium finished doses by our partners have rapidly increased their end-market share, with the sales volume in 2022 among the highest, reflecting the recognition of the quality of the Group's products in the United States market.

The ANDA approval indicated that Hepalink's enoxaparin sodium finished doses can be sold in the United States market by its own sales team, which will further increase the market share of the Company's enoxaparin sodium finished doses in the United States through the coverage of its own sales network and pipeline. The Company's proprietary team, Techdow USA Inc., was established in May 2021 as a wholly owned subsidiary of Hepalink and began selling standard heparin finished doses in the United States in early 2022. The team has a number of practitioners who have more than 10 years of experience in the United States pharmaceutical industry. The CEO has over 30 years of United States pharmaceutical sales experience and has worked for several global generic pharmaceutical companies. With a marketing network covering 50 states in the United States, Techdow USA Inc. currently has contracts with the three largest distributors in the United States as well as contracts with the largest Group Purchasing Organizations and dialysis centers in the United States.

We believe that the ANDA approval is another important achievement of the Group's internationalization of its finished dose pharmaceutical products business, once again demonstrating the Group's ability to enter overseas markets. In the future, with the marketing of the product, our self-operated team will continue to make efforts to further

Announcement is hereby given.

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

Shenzhen, the PRC  
March 16, 2023