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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)

## VOLUNTARY ANNOUNCEMENT ENOXAPARIN SODIUM INJECTION OBTAINS NEW MANUFACTURER AUTHORIZATION FROM EMA

This announcement is made by Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (the "Company", together with its subsidiaries, 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 the Group has been authorized as a new manufacturer of Inhixa (an enoxaparin sodium injection and one of the Group's leading drugs) by the European Medicines Agency ("EMA"), details of which are set out below:

## **DETAILS OF THE AUTHORIZATION**

(I) Product Name : Enoxaparin sodium injection

(II) Registered Product Name : Inhixa

(III) Dosage form : Injection

(IV) Strength : 20 mg/0.2 mL, 40 mg/0.4 mL, 60 mg/0.6 mL,

80mg/0.8mL, 100mg/1mL, 120mg/0.8mL,

150mg/1mL

(V) Authorized matters : Shenzhen Hepalink Pharmaceutical Group Co.,

Ltd. as a new manufacturer

(VI) Production address : No.1 Rongtian Road, Kengzi Street,

Pingshan District, Shenzhen, China

(VII) Authorization number : EMA/VR/0000262543

## BENEFIT AND IMPACT TO THE COMPANY

The new pre-filled formulation production line project at Hepalink Pingshan Park was officially kicked off in 2022. The first phase involved the construction of three pre-filled formulation production lines with a designed capacity of 330 million units per year. These production lines were designed and built according to the pharmaceutical regulatory standards of China, Europe and America, and will be used for the production of pre-filled injection solutions of Enoxaparin Sodium. Construction of the project has been completed and the Good Manufacturing Practice certificate issued by the European Union has been obtained. Please refer to the Company's announcement dated February 14, 2025 for further details.

This authorization from the EMA for the pre-filled formulation production line project at Hepalink Pingshan Park signifies that the enoxaparin sodium injections produced at this facility are now qualified for commercialization within the European Economic Area (EEA). This authorization from the EMA will provide ample capacity support for the Group's further advancement of its internationalization strategy and will effectively enhance its market competitiveness. Additionally, leveraging its strong pre-filled formulation production capacity, as well as mature self-operated sales network and channels, the Group will be able to significantly support and promote the strategy of assisting Chinese pharmaceutical enterprises in entering the European and American markets, which we believe will have a profound and positive impacts on the Company's future business expansion.

Announcement is hereby given.

By order of the Board

Shenzhen Hepalink Pharmaceutical Group Co., Ltd.

Li Li

Chairman

Shenzhen, the PRC June 17, 2025

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. Zhang Ping; and the independent non-executive directors of the Company are Dr. Lu Chuan, Mr. Huang Peng and Mr. Yi Ming.