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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 OBTAINING THE GMP CERTIFICATE FROM EMA

This announcement is made by Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (the "Company", and together with is 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 Company has recently received the "Certificate of GMP Compliance of a Manufacturer" ("GMP certificate") issued by Poland's Chief Pharmaceutical Inspector in accordance with the relevant regulations of the European Medicines Agency ("EMA"). The relevant particulars are hereby announced as follows:

## **GMP CERTIFICATE DETAILS**

Company Name : Shenzhen Hepalink Pharmaceutical Group Co., Ltd.

Production Address : No.1 Rongtian Road, Kengzi Street,

Pingshan District, Shenzhen, China

Certificate Number : ISF. 405.8.2025 MP.1 WTC/0598\_01\_01/13

Certified Production Line : PFS1-PFS3 filling production lines, PFSP1-PFSP4

packing lines

Certified Products : Enoxaparin Sodium Prefilled Injection (if any)

### IMPACT ON 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. By 2024, the project had been completed and passed the certification of GMP in the European Union (the "EU") for the first time. According to the GMP mutual recognition system among member states of the EU, passing the GMP certification indicates that the certified production lines has met the GMP standards of the EU.

Europe is an important market for the Company's global formulation business. In recent years, the market share of Enoxaparin Sodium formulations under the Group has consistently ranked among the top two in Europe. The GMP certificate granted for the new formulation production lines 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.

### RISK WARNING

The Company expects that obtaining the GMP certificate will not have a significant impact on the Company's current performance. Due to the characteristics of the pharmaceutical industry, the specific sales situation of drugs in the international market can be easily affected by changes in the market environment, exchange rate fluctuations and other factors. Shareholders and potential investors are advised to exercise caution when dealing in the shares of the Company.

Announcement is hereby given.

By order of the Board

Shenzhen Hepalink Pharmaceutical Group Co., Ltd.

Li Li

Chairman

Shenzhen, the PRC February 14, 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.