山東新華製藥股份有限公司

Shandong Xinhua Pharmaceutical Company Limited

(a joint stock company established in the People's Republic of China with limited liability)

(Stock Code: 00719)

OVERSEAS REGULATORY ANNOUNCEMENT

This overseas regulatory announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Shandong Xinhua Pharmaceutical Company Limited (the "**Company**") has published the "Announcement on having obtained the Notification of Approval of Supplementary Drug Application and Other Relevant Information" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 2 December 2024. The English translation of the relevant document is hereby included for reference. If there is any inconsistency between the English version and the Chinese version, the Chinese version shall prevail.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited
He Tongqing
Chairman

2 December 2024, Zibo, PRC

As at the date of this announcement, the Board comprises:

Executive Directors:

Mr. He Tongqing *(Chairman)*
Mr. Xu Wenhui
Mr. Hou Ning

Non-executive Directors:
Mr. Xu Lie
Mr. Zhang Chengyong

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Announcement No.: 2024-63

Shandong Xinhua Pharmaceutical Company Limited

Announcement on having obtained the Notification of Approval of Supplementary Drug Application and Other Relevant Information

The Company and its board of directors confirm that the contents of this announcement are true, accurate and complete without any false information, misleading statements or material omissions.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the *Notification of Approval of Supplementary Application concerning Drugs* (药品补充申请批准通知书) issued by the National Medical Products Administration (药品审评中心) which approved the supplementary application for the transfer of marketing authorisation holder in relation to esmolol hydrochloride injection (10ml: 0.1g) (hereinafter referred to as, the "**Product**"). The change of marketing authorisation holder of the Product was approved. Relevant information is now announced as follows:

I. Basic information

Drug name:	Esmolol hydrochloride injection
Dosage form:	Injection
Specification:	10ml: 0.1g
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Change of marketing authorisation holder
Reception number:	CYHB2401849
Drug approval number:	National Medicine Zhunzi H20243402
Notification number:	2024B05593
Approval Conclusion:	According to the *Drug Administration Law of the People's Republic of China* and applicable regulations, upon review, the application concerning the Product complies with applicable requirements for drug registration and the change of the marketing authorisation holder in connection therewith be approved in accordance with the relevant provisions of the *Measures for the Administration of Post-marketing Changes of Drugs (Trial)*.

II. Other relevant information

In December 2022, Beijing Minkang Baicao Pharmaceutical Technology Company Limited (hereinafter referred to as "**Minkang Baicao**") submitted the registration application materials in connection with the marketing authorisation of esmolol hydrochloride injection (10ml: 0.1g) to the Center for the Drug Evaluation (CDE) of the National Medical Products Administration and the application was accepted. In March 2024, the Product passed the review and approval by the National Medical Products Administration.

In July 2023, Xinhua Pharmaceutical and Minkang Baicao entered into a technology transfer contract which

stipulates that Minkang Baicao shall make an one-off transfer of its license concerning the marketing and sales of esmolol hydrochloride injection as well as all the rights and interests involved in relevant technology (including production approval documentation, intellectual property rights relating to production technology, commercialisation rights and related rights and benefits etc., including but not limited to from the aspects of production technology, sales and marketing, etc.) to Xinhua Pharmaceutical. The total technology transfer fee shall be payable by Xinhua Pharmaceutical to Minkang Baicao in accordance with staged instalments as stipulated under the contract. Pursuant to the *Rules Governing the Listing of Shares on Shenzhen Stock* Exchange (深圳证券交易所股票上市规则) and the articles of association of the Company (公司章程), the present transaction is not required to be submitted for the review and approval of the board of directors or shareholders' meeting of the Company.

The present transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the *Measures for Administration of Material Assets Reorganization of Listed Companies*(上市公司重大资产重组管理办法).

In November 2024, Xinhua Pharmaceutical submitted supplementary application materials in connection with the change of marketing authorisation holder concerning the Product to the National Medical Products Administration and the application was accepted. In December 2024, Xinhua Pharmaceutical received notification concerning approval of the supplementary drug application. The conclusion of the review evaluation is that the application for the change of marketing authorisation holder concerning the Product complies with applicable requirements of post-marketing administrative provisions, and the change of marketing authorisation holder concerning the Product was approved.

Esmolol hydrochloride injection is used to control ventricular rate during atrial fibrillation and atrial flutter, perioperative hypertension, and sinus tachycardia. The drug was first developed by Baxter Healthcare Corporation and was launched in the United States in 1986. It was later approved in Japan, Germany, the United Kingdom and other countries. The original drug has not been launched in China. According to relevant data, sales volume of esmolol hydrochloride injection in public medical institutions in China amounted to RMB 1.08 billion in 2023.

III. Impact on the Company and risk warning

The launch of esmolol hydrochloride injection (10ml:0.1g) will enrich the Company's cardiovascular and cerebrovascular product line, enhancing the Company's market competitiveness.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement processes, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest sensibly and pay attention to investment risks.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited

2 December 2024