

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 Levamlodiping besylate tablets obtaining the drug registration certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 13 December 2023. 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

13 December 2023, Zibo, PRC

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

Executive Directors:

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

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Lo Wah Wai

Non-executive Directors:

Mr. Cong Kechun
Mr. Xu Lie

Shandong Xinhua Pharmaceutical Company Limited**Announcement on levamlodiping besylate tablets (2.5mg) obtaining the drug registration certificate**

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 Drug Registration Certificate (药品注册证书) of levamlodiping besylate tablets (2.5mg) (hereinafter referred to as the “**Product**”) approved and issued by the National Medical Products Administration of the People’s Republic of China. Relevant information is now announced as follows:

(i) Basic information

Drug name:	Levamlodiping besylate tablets
Dosage form:	Tablet
Specifications:	2.5mg (calculate by C ₂₀ H ₂₅ ClN ₂ O ₅)
Drug category:	Prescription drugs
Registration category:	Class 4 chemicals
Holder of the marketing license:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Approval number:	CYHS2200840国、CYHB2301971
Drug approval number:	Guoyao Zhunzi (国药准字) H20234614
Notification number:	2023S01963
Review conclusion:	According to the Pharmaceutical Administration Law of the People’s Republic of China (中华人民共和国药品管理法) and applicable regulation, upon review, the Product conforms to applicable requirements for drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions and labelling as well as the production process concerning the Product shall be consummated in accordance with relevant documentation. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of drugs.

(ii) Other relevant information

1. In May 2022, Jiangsu Wangao Pharmaceutical Company Limited (hereinafter referred to as “**Jiangsu Wangao**”) submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning marketing license registration for domestic production of levamlodiping besylate tablets, and the application materials were accepted.

2. In February 2023, Xinhua Pharmaceutical and Jiangsu Wangao signed a production technology and holder transfer contract which stipulated that the marketing license holder in connection with the Product shall be changed to Xinhua Pharmaceutical. Xinhua Pharmaceutical subsequently became the holder of the marketing license for the Product pursuant to which it became entitled to relevant rights, including in respect of, without limitation, the product production technology, sales and market promotion. The total technology transfer fees amounted to RMB 16 million and shall be paid by Xinhua Pharmaceutical to Jiangsu Wangao in instalments in accordance with terms of the agreement.

According to the Listing Rules of Shenzhen Stock Exchange and the articles of association of the Company, this transaction does not require submission for review by the board of directors or in a shareholders' meeting.

This transaction does not constitute a related party transaction, nor does it constitute an asset restructuring as stipulated under the Measures for the Administration of Major Asset Restructuring of Listed Companies.

3. In December 2023, the Company obtained the Drug Registration Certificate (药品注册证书), and drug was approved for production following the review conclusion.
4. Levamlodipine besylate tablets are unique long-acting dihydropyridine calcium antagonist with high vascular selectivity. It performs chiral separation in the racemic molecule of amlodipine besylate, removing the dextroisomer that is prone to side reactions such as edema but does not have a hypotensive effect, while retaining the laevoisomer that has a hypotensive effect.

Levamlodipine besylate tablets belong to category B variety of the “*National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2022)*” (国家基本医疗保险、工伤保险和生育保险药品目录(2022年)). According to available data, sales of levamlodipine besylate tablets in public hospitals in Chinese cities reached RMB 5.363 billion in 2022.

(iii) Impact on the Company and risk warning

Xinhua Pharmaceutical obtained the drug registration certificate for levamlodipine besylate tablets (2.5mg) in December 2023, which is beneficial for enriching our cardiovascular and cerebrovascular drug series and enhancing our comprehensive competitive advantage.

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**

13 December 2023