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 obtaining the drug registration certificate for valsartan and amlodipine tablets(I)" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 18 May 2023, the English version 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

18 May 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

Non-executive Directors:

Mr. Cong Kechun

Mr. Xu Lie

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Lo Wah Wai

Mr. Ling Peixue

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-27

Shandong Xinhua Pharmaceutical Company Limited

Announcement on obtaining the drug registration certificate for valsartan and amlodipine tablets(I)

The Company and the 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 received the Drug Registration Certificate（《药品注册证书》）of valsartan and amlodipine tablets (I) (缬沙坦氨氯地平片) (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration.. Relevant information is now announced as follows:

I. Basic information

Drug Name: valsartan and amlodipine tablets (I)

Dosage form: Tablet

Specifications: Each tablet contains 80mg valsartan and 5mg amlodipine

Drug Category: Prescription Drugs

Registered classification: Class 4 chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Drug registration (Domestic production)

Reception Number: CYHS2102233 Guo

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20233538

Notification number: 2023S00656

Approval Conclusion: According to the Drug Administration Law of the People's Republic of China（《中华人民共和国药品管理法》）and relevant regulations, after review, the Product conforms to the relevant requirements of drug registration, and the drug registration certificate will be issued. The quality standards, instructions, labels, and production process shall be executed as attached. Pharmaceutical production enterprises should meet the requirements of the quality control standards for drug production before they can produce and sell drugs.

II. Other relevant information

In December 2021, Xinhua Pharmaceutical submitted to the Center for Drug Evaluation of the State Drug Administration ("**CDE**") (药品审评中心) for the registration of valsartan and amlodipine tablets. In September 2022, the Company received a supplementary research notice from CDE and the Company completed the supplementary research work and submitted materials in December 2022. In May 2023, the Company obtained the Drug Registration Certificate(《药品注册证书》), and the review concluded that the registration was approved.

Valsartan amlodipine tablets (I) were developed by Novartis Pharma Schweiz AG. It first received marketing authorization in the European Union on January 16, 2007, under the trade name Exforge, and was approved domestically on September 29, 2009.

Valsartan amlodipine tablets (I) is used for the treatment of essential hypertension in patients whose blood pressure cannot be fully controlled by a single drug therapy. It belongs to the category B 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 relevant statistics, in 2022, the total sales of valsartan amlodipine tablets (I) at Chinese public medical institutions and Chinese urban drug stores exceeded RMB1.68 billion.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's valsartan amlodipine tablets (I) has obtained the Drug Registration Certificate in May 2023, which enriched the cardiovascular and cerebrovascular drug market of the company and created new profit growth points.

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

By Order of the Board

Shandong Xinhua Pharmaceutical Company Limited

18 May 2023