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 Memantine Hydrochloride Tablets Obtaining the Drug Registration Certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 19 January 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

19 January 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
Mr. Cheung Ching Ching, Daisy

Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2024-07

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Memantine Hydrochloride Tablets 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 received the Drug Registration Certificate（药品注册证书） of memantine hydrochloride tablets (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: Memantine hydrochloride tablets

Dosage form: Tablets

Specifications: 10mg

Drug category: Prescription drugs

Registration category: Class 4 chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application matter: Drug registration (Domestic production)

Approval number: CYHS2101813国、CYHB2301401

Drug registration standard number: YBH21152023

Certificate number: 2024S00079

Drug approval number: Guoyao Zhunzi (国药准字) H20243056

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 application regulation, upon review, the Product conforms to the relevant requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, instructions, labels, and production process 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 September 2021, Beijing Minkang Baicao Pharmaceutical Technology Company Limited (hereinafter referred to as "**Beijing Minkang Baicao**") submitted the application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for the marketing of memantine hydrochloride tablets for domestic production and the application was accepted.

(2) In November 2022, Xinhua Pharmaceutical and Beijing Minkang Baicao entered into a production

technology and holder transfer contract for the Product. Xinhua Pharmaceutical will become the marketing license holder of the Product and enjoy relevant rights and interests, including but not limited to product production, sales, market promotion, etc. The Company will pay the relevant transfer fee to Beijing Minkang Baicao in stages according to the agreement and the total technology transfer fee is RMB 4.8 million.

Pursuant to the Rules Governing the listing of Stock on Shenzhen Stock Exchange (《深圳证券交易所股票上市规则》) and the Articles of Association (《公司章程》), the transaction is not required to be submitted to the Company's board of directors and shareholders' meeting for approval.

The 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》).

(3) In January 2024, Xinhua Pharmaceutical obtained the Drug Registration Certificate(《药品注册证书》), and the review conclusion was approved for production.

(4) Memantine hydrochloride tablets are used to treat moderate to severe Alzheimer's disease in adult patients, and is a category B variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2023 年)》). According to relevant data, in 2022, sales revenue of Memantine preparation in public hospital in Chinese cities reached RMB 247 million, of which the sales revenue of tablets reached RMB 222 million in monetary terms.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's memantine hydrochloride tablets (10mg) have obtained the Drug Registration Certificate in January 2024, which is beneficial for enriching the product line of elderly medication and enhancing the market competitiveness of the Company.

It is hereby announced that 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

19 January 2024