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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**”) will publish the “Announcement on Memantine hydrochloride oral solution having obtained the drug registration certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 24 April 2025. 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

23 April 2025 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

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Memantine hydrochloride oral solution having obtained 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 Memantine hydrochloride oral solution (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:	Memantine hydrochloride oral solution
Dosage form:	Oral solution
Specifications:	360ml: 0.72g
Drug category:	Prescription drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2302462
Drug approval number:	National Medicine Zhunzi (国药准字)H20253925
Certificate number:	2025S01075
Review conclusion:	In accordance with the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and relevant regulation, upon review, the Product conforms with the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labelling as well as 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

In September 2023, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning marketing of Memantine hydrochloride oral solution for domestic production and the application materials were accepted. In April 2025, Xinhua Pharmaceutical obtained the Drug Registration Certificate (药品注册证书), and the review conclusion was

that is shall be approved for registration.

Memantine hydrochloride oral solution is used to treat moderate to severe Alzheimer’s dementia. It belongs to the Class B variety of “National Basic Medical Insurance, Industrial Injury Insurance, and Maternity Insurance Drug List (2024)”. According to relevant statistics, the sales of Memantine in China’s public medical institutions amounted to RMB 402 million in 2023.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's Memantine Hydrochloride Oral Solution obtained a drug registration certificate in April 2025, which is beneficial to enrich the product series of elderly medication and enhancing the 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**
23 April 2025