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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 Oseltamivir Phosphate for Suspension having obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 24 December 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 December 2025, Zibo, the People's Republic of China

As at the date of this announcement, the board of directors of the Company comprises:

Executive Directors:

Mr. He Tongqing (*Chairman*)

Mr. Xu Wenhui

Mr. Hou Ning

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Ling Peixue

Ms. Cheung Ching Ching, Daisy

Non-executive Directors:

Mr. Xu Lie

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Oseltamivir Phosphate for Suspension having obtained
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) in connection with its Oseltamivir Phosphate for Suspension (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:	Oseltamivir Phosphate for Suspension
Dosage form:	Oral Suspension
Specifications:	0.36g (calculated based on C ₁₆ H ₂₈ N ₂ O ₄)
Drug category:	Over-the-counter drugs
Registered classification:	Class 3 chemicals
Applicant:	Shandong Zibo Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2401142
Drug approval number:	National Medicine Zhunzi (国药准字) H20256303
Certificate number:	2025S03820
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, labels as well as production process concerning the Product shall be consummated in accordance with relevant documentation. The product should undergo a pre-market drug production quality management compliance inspection.

II. Other relevant information

In March 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Oseltamivir Phosphate for Suspension, and the application materials were accepted. In December 2025, Xinhua Pharmaceutical obtained the *Drug Registration Certificate*, and the review conclusion was that the Product shall be approved for registration.

The Product is used for the treatment of influenza A and B in patients aged two weeks and above who have been symptomatic for no more than 48 hours (Oseltamivir phosphate can effectively treat influenza A and B, but there is still a lack of clinical application data for influenza B). The Product is also indicated for prophylaxis of influenza A and B in people who are aged one year and above.

The Product is listed in the "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2024)" as a Category B product. According to relevant statistics, the sales of Oseltamivir Phosphate for Suspension in China's public medical institutions amounted to approximately RMB 5.9 billion in 2024.

III. Impact on the Company and risk warning

The obtaining of approval of *Drug Certification Certificate* by Xinhua Pharmaceutical in December 2025 in connection with its Oseltamivir Phosphate for Suspension applied for is conducive to enriching the antiviral drug product line of the Company and enhancing its comprehensive 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 December 2025