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 Peramivir Injection having obtained the Notification of Approval of Supplementary Drug Application (《药品补充申请批准通知书》)" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 8 April 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

8 April 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
Ms. Cheung Ching Ching, Daisy

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2024-17

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Peramivir Injection having obtained the Notification of Approval of Supplementary Drug Application

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 *Notification of Approval of Supplementary Drug Application* (《药品补充申请批准通知书》) issued by the National Medical Products Administration in connection with the approval of marketing authorisation holder (MAH) transfer application in relation to the Peramivir Injection (15ml: 0.15g) (hereinafter referred to as the "**Product**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Peramivir Injection
Dosage form:	Injection
Specifications:	15ml:0.15g (according to $C_{15}H_{28}N_4O_4$)
Drug category:	Prescription drugs
Registered classification:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Supplementary Application (Change of Marketing Authorisation Holder)
Case number:	CYHB2400368
Original drug approval number:	Guoyao Zhunzi (《国药准字》) H20243128
Notification number:	2024B01462
Approval Conclusion:	In accordance with the *Drug Administration Law* of the People's Republic of China and relevant regulation, after examination, the application for the Product meets the relevant requirements for drug registration and the change of the marketing permit holder of this product from "Suzhou Amerigen Pharmaceutical Co., Ltd." to "Shandong Xinhua Pharmaceutical Co., Ltd." in accordance with the relevant provisions of the *Measures for the Administration of Changes after Drug Listing (Trial)* has been approved, with the drug approval number unchanged.

II. Other relevant information

1. In June 2022, Suzhou Amerigen Pharmaceutical Co., Ltd. (hereinafter referred to as "**Suzhou Amerigen**") submitted application materials for market approval registration of Paramivir Injection (15ml: 0.15g) to the Center for Drug Evaluation of the State Drug Administration (药品审评中心)

and the said application was accepted.

2. In March 2023, Xinhua Pharmaceutical entered into a production technology and holder transfer contract with Suzhou Amerigen which stipulates that the marketing license holder of the Product shall be transferred from Suzhou Amerigen to Xinhua Pharmaceutical, and Xinhua Pharmaceutical shall become the ultimate marketing license holder of the Product with entitlement to relevant rights and benefits concerning, without limitation, product production technology, sales, market promotion, etc. The total technology transfer fee is RMB 8.5 million which shall be payable by Xinhua Pharmaceutical to Suzhou Amerigen in instalments in accordance with the contract.

   According 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 of the Company (《公司章程》), this transaction is not required to be submitted for review by the Company's board of directors or shareholders meeting. The transaction does not constitute a connected transaction, nor does it constitute a material asset reorganisation under the *Administrative Measures for the Material Asset Reorganisation of Listed Companies* (《上市公司重大资产重组管理办法》.

3. In March 2024, Xinhua Pharmaceutical submitted supplementary application materials concerning change of marketing license holder relating to the Product to the National Medical Products Administration and the application was accepted. This supplementary application was approved in April 2024.

4. Paramivir is a new generation of neuraminidase inhibitor, which can selectively inhibit the neuraminidase of human influenza A and B viruses, inhibit the mature influenza virus from leaving the host cell, so as to inhibit the spread of influenza virus in the human body and play a role in the treatment of influenza, mainly used in the treatment of influenza A or B.

   The original research of Paramivir Injection has not yet been imported into China.According to relevant data, sales revenue of Paramivir Injection in Chinese urban public hospitals in the first half of 2023 amounted to RMB 694 million.

III. Impact on the Company and risk warning

The listing of Xinhua Pharmaceutical's Paramivir Injection (15ml: 0.15g) is conducive to enriching the Company's series of anti infective drugs and enhancing its overall 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

8 April 2024