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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**") has published the "Announcement on Naloxone Hydrochloride Injection having passed the generics consistency evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 31 May 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

31 May 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

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Naloxone Hydrochloride Injection having passed the generics consistency evaluation

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 Notice of Approval of Supplementary Drug Application（《药品补充申请批准通知书》） from the National Medical Products Administration in relation to the approval of Naloxone Hydrochloride Injection (hereinafter referred to as the "**Product**"), which has passed the "Consistency of Quality and Efficacy Evaluation for Generic Drugs" (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug name: Naloxone Hydrochloride Injection

Dosage form: Injection

Specifications: 1ml:0.4mg, 1ml:1mg, 2ml:2mg

Drug category: Prescription Drugs

Registration category: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application matter: Consistency of Quality and Efficacy Evaluation for Generic Drugs

Approval number: CYHB2350313, CYHB2350315, CYHB2350314

Original drug approval number: Guoyao Zhunzi (《国药准字》)H20055761,Guoyao Zhunzi(《国药准字》) H20055762, Guoyao Zhunzi(《国药准字》) H20055763

Notification number: 2024B02422、2024B02421、2024B02420

Review conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In March 2023, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning the consistency of quality and efficacy evaluation for generic drugs of naloxone hydrochloride injection and the application was accepted. In May 2024, we were granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which

concluded that we passed the consistency of quality and efficacy evaluation for generic drugs.

Naloxone hydrochloride injection was developed by ADAPT Pharmaceuticals in the United States. The reference preparations of the Product published by the National Medical Products Administration are certified by Hospira Inc (1ml:0.4mg) and International Medication Systems, Limited (2ml:2mg) listed in the Orange Book of the United States. The Product is available in the United States and Japan, but has not yet been approved for import in China.

Naloxone hydrochloride injection is an opioid receptor antagonist used to reverse the respiratory depression caused by opioid drugs after combined anesthesia, promote patient recovery, completely or partially reverse the respiratory depression caused by opioid drugs in cases of opioid overdose, rescue acute alcohol intoxication, and diagnose acute opioid overdose.

As an antidote, naloxone hydrochloride injection has been included in the 2023 version of the national medical insurance class A drug list. According to relevant statistics, the sales of naloxone-related preparations in urban public hospitals in China in 2023 was about RMB 912 million.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's Naloxone Hydrochloride Injection (1ml:0.4mg,1ml:1mg, 2ml:2mg) has passed the consistency of quality and efficacy evaluation for generic drugs in May 2024, which will help further enhance the Product's 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

31 May 2024