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 Pentazocine Having Obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 4 November 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

4 November 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 Announcement No.: 2024-58

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Pentazocine Having Obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs

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 Marketing Application for Chemical Substance Drugs (化学原料药上市申请批准通知书) in connection with its pentazocine (hereinafter referred to as, the "**Product**") which was approved and issued by the National Medical Products Administration (国家药品监督管理局) ("**NMPA**"). The Company is the third enterprise in China that has passed the approval of this active pharmaceutical ingredients, and the relevant information is hereby announced as follows:

I. Basic information

Drug name:	Pentazocine
Dosage form:	Active Pharmaceutical Ingredients
Registration classification:	Chemical drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application natter:	Application for the Listing of Domestic Production of Chemical Raw Materials
Acknowledgement number:	CYHS2360213
Registration number:	Y20220001328
Notification number:	2024YS01122
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 applicable regulation, upon review, the Product conforms to applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation.

II. Other relevant information

In February 2023, Xinhua Pharmaceutical submitted an application for the registration of pentazocine (i.e. the Product) to the Center for Drug Evaluation of the NMPA and such application was acknowledged. In November 2024, Xinhua Pharmaceutical obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

The Product was developed by Sterling Winslip (now Sanofi) in the United States and has been registered and

marketed in the People's Republic of China and abroad. The injection was originally researched by Maruishi Pharmaceutical Company Limited and has been approved for marketing in Japan in March 1970 with specifications of 1ml:30mg and 1 ml:15 mg, which is a generic drug reference preparation announced by the NMPA. Its original research has not been imported into China.

The Product is a type of refined hemp drugs and is suitable for use in respect of all kinds of pain, such as cancer pain, traumatic pain and postoperative pain. The Product can be administered prior to operations or application of anesthesics, as an auxiliary medicine for surgical anesthesia.

III. Impact on the Company and risk warning

The approval of the Product indicates that this active pharmaceutical ingredients has met relevant national drug evaluation technical standards and has been approved for use based on domestic formulations. This will further enrich the refined hemp product line of the Company and enhance its core 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

4 November 2024