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 Tramadol Hydrochloride Sustained-release Tablets passing the Generic Drugs Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 11 January 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

10 January 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

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2025-03

Shandong Xinhua Pharmaceutical Company Limited
Announcement in connection with Tramadol Hydrochloride Sustained-release Tablets passing the Generic Drugs 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 *Notification 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 Tramadol Hydrochloride Sustained-release Tablets (hereinafter referred to as the "**Product**"), having passed the "Consistency of Quality and Efficacy Evaluation for Generic Drugs" (仿制药质量和疗效一致性评价). Xinhua Pharmaceutical is the first domestic enterprise to pass the consistency evaluation of generic drugs for the Product. Relevant information is now announced as follows:

I. Basic information

Drug name:	Tramadol Hydrochloride Sustained-release Tablets
Dosage form:	Tablets
Specifications:	0.1g
Drug category:	Prescription drugs
Registered classification:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Consistency of Quality and Efficacy Evaluation for Generic Drugs
Case number:	CYHB2450065
Drug approval number:	Guoyao Zhunzi (国药准字) 19990062
Certificate number:	2025B00017
Review conclusion:	The Product has passed the Consistency of Quality and Efficacy Evaluation for Generic Drugs

II. Other relevant information

In January 2024, Shandong Xinhua Pharmaceutical Company Limited submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) in connection with consistency of quality and efficacy evaluation for the generic drug, Tramadol Hydrochloride Sustained-release Tablets, and the application was accepted. In January 2025, Shandong Xinhua Pharmaceutical Company Limited was granted the Notication of Approval of Supplementary Drug Application (药品补充申请批准通知书), which concluded that the Product passed the consistency of quality and efficacy evaluation for generic drugs.

The Product is a centrally acting opioid analgesic, indicated for moderate to severe pain. Tramadol extended-release tablets as an opioid, and belong to category B variety of the "National Essential Medicines List" and "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2024)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2024 年)》). According to relevant data, in 2023, the sales of tramadol in China public medical institutions reached RMB 913 million.

III. Impact on the Company and risk warning

The passing of consistency evaluation of generic drug quality and efficacy in January 2025 concerning tramadol hydrochloride sustained-release tablets of Shandong Xinhua Pharmaceutical Company Limited is conducive in enhancing the market competitiveness of the Product.

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
10 January 2025