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 obtaining the Notice of Approval for Drug Clinical Trials" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 23 June 2026. 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

22 June 2026, 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

Non-executive Directors:

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 obtaining the Notice of Approval for Drug Clinical Trials

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 for Drug Clinical Trials* in connection with its LXH-2103 injection (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:	LXH-2103 injection
Dosage form:	Injection
Specifications:	1ml: 50mg
Drug category:	Prescription drugs
Registered classification:	Class 1 chemical drug
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Clinical trials)
Case number:	CXHL2600424
Notification number:	2026LP01818
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 regulations, upon review, the application for clinical trial of the LXH-2103 injection accepted on 9 April 2026 meets the relevant requirements for drug registration and it is agreed that clinical trials for the treatment of moderate to severe postoperative pain may proceed.

II. Other relevant information

In November 2025, Xinhua Pharmaceutical submitted an application to the Center for Drug Evaluation (CDE) of the National Medical Products Administration for a consultation meeting concerning clinical trials for the Product. In March 2026, CDE provided feedback on the issues submitted for discussion, and in the same month, the Company submitted an application for clinical trials in connection with the Product, which application was accepted in April. In June 2026, the *Notice of Approval for Drug Clinical Trials* was obtained, with the review concluding that approval was granted for the clinical trials to proceed.

LXH-2103 injection is a Class 1 innovative drug developed by Xinhua Pharmaceutical for the treatment of moderate to severe postoperative pain. As a novel analgesic, it is designed to resolve interindividual differences in the efficacy and safety of conventional opioids (such as hydrocodone, codeine and tramadol) arising from CYP2D6 genetic polymorphism. Studies have shown that LXH-2103 functions as a biased mu-opioid receptor (MOR) agonist. This property allows the Product to bypass the influence of CYP2D6 genetic polymorphism while offering significant analgesic potential and a superior safety profile.

III. Risk warning

The Company will conduct clinical trials in strict accordance with the requirements as specified in the approval document. Upon the completion of clinical trials, the Company will submit a clinical trial report and relevant documents to the National Medical Products Administration to apply for production registration approval.

The research and development of pharmaceutical products (including clinical trials), and the whole process from registration application to industrial production (involving a lengthy cycle with multiple stages), may be affected by various uncertainties including, without limitation, technical issues and review procedures, and the competitive landscape of future products may also evolve. The Company will closely monitor the actual progress of the drug registration application in connection with the Product and fulfil its information disclosure obligations in a timely manner.Investors are reminded to make rational investment decisions and pay attention to investment risks.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited
22 June 2026