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 (hereinafter "**Xinhua Pharmaceutical**" or, the "**Company**") will publish the "Announcement on obtaining Notice of Approval for Drug Clinical Trials" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 26 September 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*

25 September 2025 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. 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 obtaining 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.

The Company has recently received the *Notice of Approval for Drug Clinical Trials* in connection with its LXH-1211 tablets (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-1211 tablets |
| Dosage form: | Tablet |
| Specifications: | 0.5mg; 1mg; 2mg; 5mg |
| Drug category: | Prescription drugs |
| Registered classification: | Class I chemicals |
| Applicant: | Shandong Xinhua Pharmaceutical Company Limited |
| Application matter: | Drug registration (Clinical trials) |
| Case number: | CXHL2500671, CXHL2500672, CXHL2500673, CXHL2500674 |
| Notification number: | 2025LP02497, 2025LP02498, 2025LP02499, 2025LP02500 |
| 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 regulation, upon review, the application for clinical trials of LXH-1211 tablets that was accepted on 10 July 2025 conforms with the relevant requirements of drug registration and it is agreed that clinical trial of the Product for treating pulmonary arterial hypertension may be carried out. |

## II. Other relevant information

In September 2024, Xinhua Pharmaceutical submitted an application to the Center for Drug Evaluation (CDE) of the National Medical Products Administration for a meeting in connection with dialogue concerning clinical trials of the Product. In December 2024, CDE provided feedback in connection with issues that were submitted, and in July 2025, the Company submitted an application for clinical trials of the Product, and the application was accepted. In September 2025, the Company obtained the *Notice of Approval for Drug Clinical Trials*, and the review conclusion was that the Product shall be approved for clinical trials.

On 21 December 2020, Xinhua Pharmaceutical signed a *Technology Transfer Contract* with the Central South University in connection with the research and development of the innovative drug LXH-1211 for treatment of anti-pulmonary arterial hypertension. For details, please refer to the "Announcement regarding the Company having signed the *Technology Transfer Contract* with Central South University" (Announcement No. 2020-52) on the CNINFO website.

LXH-1211 tablets are structurally novel compounds designed to address the clinical manifestations and pathological nature of pulmonary arterial hypertension. Studies have shown that LXH-1211 has a dual action

mechanism that can produce vasodilation effects by stimulating soluble guanylate cyclase (sGC) to reduce pulmonary arterial hypertension as well as prevent vascular remodeling and fibrosis processes by inhibiting AMP-activated protein kinase (AMPK). The proposed clinical indication for the Product is pulmonary arterial hypertension.

## III. Impact on the Company and 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 the clinical trial report and relevant documents to the National Medical Products Administration to apply for the production registration approval document.

The research and development of medical 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 such as, without limitation, technical issues and review procedures, and the competitive landscape of prospective products may also evolve. The Company will closely monitor the actual progress of the drug registration application in connection with the Product and fulfill 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**
25 September 2025