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 having obtained the Notification of Approval of Supplementary Drug Application and Other Relevant Information" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 4 March 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

3 March 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 Announcement No.: 2025-08

Shandong Xinhua Pharmaceutical Company Limited

Announcement on having obtained the Notification of Approval of Supplementary Drug Application and Other Relevant Information

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 Application concerning Drugs* (药品补充申请批准通知书) issued under the authority of the National Medical Products Administration (国家药品监督管理局) which approved the supplementary application for the transfer of marketing authorisation holder of Clopidogrel Hydrogen Sulfate Tablets (hereinafter referred to as, the "**Product**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Clopidogrel Hydrogen Sulfate Tablets
Dosage form:	Tablet
Specification:	75mg (calculated based on $C_{16}H_{16}ClNO_2S$)
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Change of marketing licence holder
Reception number:	CYHB2500234
Drug approval number:	National Medicine Zhunzi H20213840
Notification number:	2025B00794
Approval Conclusion:	According to the *Drug Administration Law of the People's Republic of China* and applicable regulations, upon review, the application concerning the Product complies with applicable requirements for drug registration and it is agreed that the change of the marketing licence holder in connection therewith be approved in accordance with the relevant provisions of the *Measures for the Administration of Post-marketing Changes of Drugs (Trial)*.

II. Other relevant information

In March 2024, Xinhua Pharmaceutical and Beijing Sihuan Pharmaceutical Company Limited (hereinafter referred to as "**Beijing Sihuan**") entered into a technology transfer contract, which stipulates that Beijing Sihuan shall make an one-off transfer of its license concerning the marketing and sales of Clopidogrel Hydrogen Sulfate Tablets as well as all the rights and interests involved in the relevant technology (including production approval documentation, intellectual property rights relating to production technology, commercialisation rights and related rights and benefits etc., including but not limited to from the aspects of production technology, sales and marketing, etc.) to Xinhua Pharmaceutical. The total technology transfer fee shall be payable by Xinhua Pharmaceutical to Beijing Sihuan in accordance with staged instalments as

stipulated under the contract. Pursuant to the *Rules Governing the Listing of Shares on Shenzhen Stock Exchange* (深圳证券交易所股票上市规则) and the articles of association of the Company (公司章程), the present transaction is not required to be submitted for the review and approval of the board of directors or shareholders' meeting of the Company.

The present transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the *Measures for Administration of Material Assets Reorganization of Listed Companies* (上市公司重大资产重组管理办法).

In January 2025, Xinhua Pharmaceutical submitted supplementary application materials in connection with the change of marketing license holder of the Product to the National Medical Products Administration, and in February 2025, it received notification concerning approval of the supplementary drug application. The conclusion of the review evaluation is that the application for the transfer of holder of the Product complies with applicable requirements of post-listing administrative provisions, and the change of marketing licence holder of the Product was approved.

Clopidogrel hydrogen sulfate tablet is a drug used for treatment of circulatory diseases and is a prodrug. One of its metabolites is a platelet aggregation inhibitor. Chlorella must be metabolised by CYP450 enzyme to generate active metabolites that can inhibit platelet aggregation. The active metabolite of clopidogrel selectively inhibits the binding of diphosphate (ADP) to its platelet P2Y12 receptor and the secondary ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thus inhibiting platelet aggregation. The drug is suitable to treat the following types of patients to prevent atherosclerotic thrombosis events: patients with recent myocardial infarction (from a few days to less than 35 days), patients with recent ischemic stroke (from 7 days to less than 6 months) or patients that have a confirmed peripheral arterial diagnosis; patients with acute coronary syndrome: non-ST segment elevation acute coronary syndrome (including unstable angina or non-Q wave myocardial infarction), including patients with stents placed after percutaneous coronary intervention, used in combination with aspirin; used in patients with ST-segment elevation acute coronary syndrome, combined with aspirin, and can be used in thrombolytic therapy. According to relevant data, the annual sales of Clopidogrel Hydrogen Sulfate Tablets in Chinese public medical institutions in 2023 was approximately RMB 5.943 billion; and the sales in the first half of 2024 was approximately RMB 3.216 billion, of which 75mg sales accounted for 89.01%.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical became the marketing license holder of the Product following the approval of Clopidogrel Hydrogen Sulfate Tablets by the National Medical Products Administration in February 2025. The inclusion of this Product which may be marketed by the Company enriches its circulation system product line 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

3 March 2025