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 22 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

21 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 Announcement No.: 2025-06

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) in connection with its Rosuvastatin calcium tablets (20mg;10mg) (hereinafter referred to as, the "**Product**") which was issued under the authority of the National Medical Products Administration (药品审评中心). The change of marketing licence holder of the Product was approved. Relevant information is now announced as follows:

I. Basic information

Drug name:	Rosuvastatin calcium tablets
Dosage form:	Tablet
Specification:	20mg, 10mg (calculated based on $C_{22}H_{28}FN_30_6S$)
Drug classification:	Prescription drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Change of marketing licence holder
Reception number:	CYHB2402222, CYHB2402223
Drug approval number:	National Medicine Zhunzi H20234598, National Medicine Zhunzi H20247200
Notification number:	2025B00208, 2025B00209
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

Xinhua Pharmaceutical and Suzhou Dongrui Pharmaceutical Company Limited (hereinafter referred to as "**Suzhou Dongrui**") signed a technology transfer contract in May 2024. According to the contract, Suzhou Dongrui shall make an one-off transfer of its license concerning the marketing and sales of Rosuvastatin calcium tablets (20mg;10mg) and all the rights and interests involved in relevant technology (including production approval documentation, intellectual property rights relating to production technology, commercialization 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 Suzhou Dongrui 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 December 2024, Xinhua Pharmaceutical submitted application materials in connection with the change of marketing license holder of the Product to the National Medical Products Administration Drug Evaluation Center (CDE), and in January 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.

The Product is suitable for patients with primary hypercholesterolemia (type IIa, including heterozygous familial hypercholesterolemia) whose dyslipidemia cannot be adequately controlled by diet control and other non-drug treatments (such as exercise therapy, weight loss) or Mixed dyslipidemia (type IIb). The Product can delay the progression of atherosclerosis in adult patients while undergoing lipid-lowering treatment. It is also indicated for use in patients with homozygous familial hypercholesterolemia as an adjunct to dietary control and other lipid-lowering measures (such as LDL depletion therapy), or when these methods are not suitable. According to relevant statistical data, the annual sales of Rosuvastatin calcium tablets in China's public medical institutions in 2023 reached RMB 1.159 billion and the sales in the first half of 2024 reached RMB 613 million, of which 10mg sales account for 94.79%.

III. Impact on the Company and risk warning

Rosuvastatin calcium tablets (20mg;10mg) was approved by the National Medical Products Administration in January 2025, and Xinhua Pharmaceutical became the marketing license holder of the Product. The inclusion of marketing of this Product enriches the Company's blood lipid regulator statin 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

21 January 2025