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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 Sacubitril Valsartan Sodium Tablets having obtained Drug Registration Certificate*” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 9 October 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

8 October 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

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Non-executive Director:

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Sacubitril Valsartan Sodium Tablets having obtained Drug Registration Certificate

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 “**Xinhua Pharmaceutical**” or, the “**Company**”) has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Sacubitril Valsartan Sodium 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:	Sacubitril Valsartan Sodium Tablets
Dosage form:	Tablets
Specifications:	For Sacubitril Valsartan 50mg (Sacubitril 24mg / Valsartan 26mg)
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2501636
Drug approval number:	National Medicine Zhunzi (国药准字) H20266108
Certificate number:	2026S03596
Review conclusion:	In accordance with the <i>Pharmaceutical Administration Law of the People's Republic of China</i> (中华人民共和国药品管理法) and relevant regulations, upon review, the Product conforms with the applicable requirements of drug registration, the drug registration is approved, and the <i>Drug Registration Certificate</i> has been issued. The standard of quality, product instructions, labels as well as production processes concerning the Product shall be consummated in accordance with relevant documentation. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of drugs.

II. Other relevant information

In April 2025, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the National Medical Products Administration (药品审评中心) (CDE) concerning the marketing of Sacubitril Valsartan Sodium Tablets and the application materials were accepted. In October 2026, Xinhua Pharmaceutical obtained the *Drug Registration Certificate*, and the review conclusion was that the Product shall be approved for registration.

The Product is indicated for adult patients with chronic heart failure with reduced ejection fraction (NYHA class II-IV, LVEF $\leq$ 40%) to reduce the risk of cardiovascular death and hospitalization for heart failure. The Product can replace angiotensin-converting enzyme inhibitors (ACEI) or angiotensin II receptor blockers (ARB) in combination with other drugs for the treatment of heart failure.

The Product is listed in the “National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)” as a Category B product. According to relevant statistics, the sales of Sacubitril Valsartan Sodium Tablets in China’s public medical institutions amounted to approximately RMB7.8 billion in 2025.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical’s obtaining of *Drug Registration Certificate* in connection with Sacubitril Valsartan Sodium Tablets in October 2026 will enrich the anti-hypertension product series of the Company and enhance its comprehensive 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**
8 October 2026