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 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 27 August 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

26 August 2025 Zibo, the 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

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 referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the *Drug Registration Certificate* (药品注册证书) for 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:	Tablet
Specifications:	Sacubitril valsartan 100mg (sacubitril 49mg/ valsartan 51mg)
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2401428
Drug approval number:	National Medicine Zhunzi (国药准字) H20255131
Notification number:	2025S02496
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 Product conforms with the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labels as well as production process 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 May 2024, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Sacubitril Valsartan Sodium tablets and the application materials were accepted. In August 2025, Xinhua Pharmaceutical obtained the *Drug Registration Certificate*, and the review conclusion was that the Product shall be approved for

registration.

Sacubitril Valsartan Sodium tablets are used in adult patients with chronic heart failure (NYHA grade II-IV, LVEF≤40%) with reduced ejection fraction to reduce the risk of cardiovascular death and hospitalization for heart failure. Sacubitril Valsartan Sodium tablets can replace angiotensin-converting enzyme inhibitors (ACEI) or angiotensin II receptor antagonists (ARB) and can be used in combination with other heart failure treatment drugs. Sacubitril Valsartan Sodium tablets can also be used to treat essential hypertension.

The Product is a compound drug of angiotensin II antagonists, and it belongs to the Class B variety of "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)". According to relevant statistics, sales of Sacubitril Valsartan Sodium tablets in China′s public medical institutions amounted to approximately RMB 4.9 billion in 2024.

III. Impact on the Company and risk warning

The obtaining by Xinhua Pharmaceutical of the *Drug Registration Certificate* for its Sacubitril Valsartan Sodium tablets in August 2025 will serve to enrich the Company's drugs for the treatment of cardiovascular diseases and enhance the Company's overall competitive advantage.

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

26 August 2025