**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 having obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 12 June 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*

11 June 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 Pharmaceutical Announcement No.: 2025-36

**Shandong Xinhua Pharmaceutical Company Limited**

**Announcement on Sacubitril Valsartan Sodium having obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs**

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 Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书) issued under the authority of National Medical Products Administration ("**NMPA**") in connection with its Sacubitril Valsartan Sodium (hereinafter referred to as the "**Product**"). Relevant information is now announced as follows:

## I. Basic information

| | |
|---|---|
| API name: | Sacubitril Valsartan Sodium |
| Applicant: | Shandong Xinhua Pharmaceutical Company Limited |
| Application natter: | Application for the Listing of Domestic Production of Chemical Raw Materials |
| Reception number: | CYHS2360783 |
| Registration number: | Y20230000980 |
| Notification number: | 2025YS00452 |
| Review conclusion: | According to the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and applicable regulation, upon review, the Product conforms with applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation. |

## II. Other relevant information

In October 2023, Xinhua Pharmaceutical submitted an application to the Center for Drug Evaluation of the National Medical Products Administration for the registration of Sacubitril Valsartan Sodium (i.e. the Product) and such application was accepted. In June 2025, Xinhua Pharmaceutical obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

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 its preparation 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 of approval by the Product will help enhance the overall competitiveness of the Company in the field of cardiovascular disease treatment.

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**
11 June 2025