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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 Bisoprolol Fumarate Tablets having obtained Drug Registration Certificate” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 14 October 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

13 October 2025 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 Directors:

Mr. Xu Lie

Mr. Zhang Chengyong

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Bisoprolol Fumarate 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) in connection with its Bisoprolol Fumarate 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:	Bisoprolol Fumarate Tablets
Dosage form:	Tablet
Specifications:	5mg; 2.5mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2400705、CYHS2400706
Drug approval number:	National Medicine Zhunzi (国药准字) H20255640; National Medicine Zhunzi (国药准字) H20255641
Notification number:	2025S03071;2025S03072
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 February 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 Bisoprolol Fumarate Tablets and the application materials were accepted. In October 2025, Xinhua Pharmaceutical obtained the

Drug Registration Certificate, and the review conclusion was that the Product shall be approved for registration.

Bisoprolol Fumarate Tablets are indicated for the treatment of hypertension, coronary heart disease (angina pectoris), and chronic stable heart failure accompanied by decreased left ventricular systolic function (ejection fraction $\leq 35\%$). When using this Product, it is necessary to follow a medical doctor's advice in receiving ACE inhibitors, diuretics and selective use of cardiac glycosides for treatment.

Bisoprolol Fumarate Tablets belong to the Class A variety of "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2024)". According to relevant statistics, sales of bisoprolol fumarate tablets in China's public medical institutions amounted to approximately RMB 1.228 billion in 2024.

III. Impact on the Company and risk warning

The approval of the Product further enriches the Company's cardiovascular and cerebrovascular product line and provides more options for clinical drug use.

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**
13 October 2025