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 Empagliflozin Tablets (10mg) Having Obtained the Drug Registration Certificate" 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 Annoucement No.: 2025- 07

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Empagliflozin Tablets (10mg) Having Obtained the 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）of empagliflozin tablets (10 mg) (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. The Product meets the relevant requirements of drug registration, has been approved for registration. Relevant information is now announced as follows:

I. Basic information

Drug name:	Empagliflozin Tablets
Dosage form:	Tablets
Specifications:	10mg
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug Registration (Domestic production)
Case number:	CYHS2302760
Drug approval number:	Guoyaozhunzi H20253201
Certificate number:	2025S00233
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 meets the relevant requirements of drug registration, has been approved for registration and issued a drug registration certificate. The standard of quality, instructions, labels, and production process 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 June 2023, Shandong Xinhua Pharmaceutical Company Limited submitted the application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for the marketing of empagliflozin tablets (10mg) for domestic production and the application was accepted. In January 2025, Shandong Xinhua Pharmaceutical Company Limited obtained the Drug Registration Certificate(《药品注册证书》), and the review conclusion was approved for registration.

Empagliflozin is a sodium-glucose cotransporter-2 (SGLT-2) inhibitor jointly developed by Boehringer Ingelheim and Eli Lilly. It reduces glucose reabsorption in the kidneys, lowers the renal glucose threshold, and promotes the direct excretion of glucose from the urine. It can also reduce sodium reabsorption and increase sodium transport to the distal tubules. Empagliflozin tablets are suitable for the treatment of type 2 diabetes, used in adult patients with symptomatic chronic heart failure to reduce the risk of hospitalization due to heart failure.

Empagliflozin tablets is a category B variety of the "National Essential Medicines List" and "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2024)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2024 年)》). According to relevant statistical data, in 2023, the sales of empagliflozin tablets (10mg) in China's public medical institutions was approximately RMB 610 million .

III. Impact on the Company and risk warning

Shandong Xinhua Pharmaceutical Company Limited's empagliflozin tablets (10mg) were approved in January 2025. The approval of the Product for marketing will further enrich the Company's product system in the field of diabetes and heart failure treatment, provide more choices for clinical medication, and enhance the Company's brand effect and market competitiveness.

It is hereby announced that 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