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**") has published the "Announcement on Having Obtained FDA approval of Abbreviated New Drug Application (ANDA)" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 28 October 2024. 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

28 October 2024, 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.: 2024-49

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Having Obtained FDA approval of Abbreviated New Drug Application (ANDA)

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 Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received an approval letter from the U.S. Food and Drug Administration (FDA) in connection with its Abbreviated New Drug Application (ANDA) relating to sevelamer carbonate tablets (800 mg) (hereinafter referred to as, the "**Product**"). The relevant information is hereby announced as follows:

I. Basic information

Drug name:	Sevelamer carbonate tablets
Dosage form:	Tablets
Specification:	800 mg
Drug classification:	Prescription drugs
Registered classification:	Abbreviated New Drug Application (ANDA)
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
ANDA number:	215998
Approval conclusion:	In accordance with section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and relevant regulation, upon review, the application concerning the Product complies with applicable requirements for drug registration under the FD&C Act. The ANDA has been approved and is effective. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of the drug.

II. Other relevant information

In June 2021, Xinhua Pharmaceutical submitted the ANDA in connection with its sevelamer carbonate tablets (800 mg) to the FDA and the application was accepted. In October 2024, the Company received an approval letter in connection with the registration of the drug, with the approval conclusion being that the ANDA has been approved and is effective.

Sevelamer carbonate tablets are used to control hyperphosphatemia in adult patients with chronic kidney disease (CKD) who are undergoing dialysis. Sevelamer carbonate tablets are non-absorbable phosphate-binding crosslinked polymer, containing no calcium or other metals, which adsorbs phosphate in the gastrointestinal tract by ion exchange, and the conjugate is excreted in the stool without systemic absorption, ensuring high safety.

Sevelamer carbonate tablets were developed by Sanofi Genzyme, and have been marketed and widely used in more than 40 countries in the United States, Japan, Canada, and Europe. Sevelamer carbonate is currently the

only new generation phosphate binder approved by the FDA that does not contain calcium or other metals. It has been consistently recommended as the preferred drug for phosphorus reduction in domestic and international guidelines. According to relevant data, sales volume of sevelamer carbonate in city public hospitals in 2023 amounted to RMB9.93 billion.

III. Impact on the Company and risk warning

The successful obtaining by Xinhua Phamaceutical in October 2024 of the approval letter from the FDA (in connection with its ANDA for registration of the drug sevelamer carbonate tablets (800mg)) expands the overseas markets of the Company and helps further enhance its market competitiveness.

The pharmaceutical sales business is susceptible to changes in 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

28 October 2024