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 of obtaining FDA registration approval letter for sevelamer carbonate (active pharmaceutical ingredients)" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 25 November 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

25 November 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.: 2024-62

Shandong Xinhua Pharmaceutical Company Limited

Announcement of obtaining FDA registration approval letter for sevelamer carbonate (active pharmaceutical ingredients)

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 approval letter from the U.S. Food and Drug Administration ("**FDA**") in connection with its sevelamer carbonate (active pharmaceutical ingredients) (hereinafter referred to as, the "**Product**"). Relevant information is hereby announced as follows:

I. Basic information

Drug name:	Sevelamer carbonate
Drug classification:	Active pharmaceutical ingredients
Registration classification:	Chemical drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for domestic production of active pharmaceutical ingredients for marketing
Drug Master File (DMF):	035326
Approval conclusion:	The marketing of sevelamer carbonate (active pharmaceutical ingredients) was approved following completion of review of the relevant DMF without identification of further issues.

II. Other relevant information

In November 2020, Xinhua Pharmaceutical submitted the DMF for the Product to the FDA and obtained a registration number. In November 2024, it received the drug registration approval letter, with the review conclusion indicating that the DMF has been approved and is effective.

Sevelamer carbonate are used to control hyperphosphatemia in adult patients with chronic kidney disease (CKD) who are undergoing dialysis. Sevelamer carbonate 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 statistics, the global consumption of sevelamer carbonate raw material was more than 600 tons in the 12 months ending 31 March 2024.

III. Impact on the Company and risk warning

The successful obtaining by Xinhua Phamaceutical of the drug registration approval letter from the FDA in November 2024 would benefit the Company in its expansion in overseas markets.

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

25 November 2024