

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 Co., Ltd. (the "**Company**") has published the "Announcement on sevelamer carbonate tablets obtained the drug registration certificate" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 27 February 2023, the English version 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

27 February 2023, 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. Cong Kechun
Mr. Xu Lie

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Lo Wah Wai
Mr. Ling Peixue

Stock Code: 000756

Stock Short Name: Xinhua Pharmaceutical

Announcement No.: 2023-08

Shandong Xinhua Pharmaceutical Company Limited

Announcement on sevelamer carbonate tablets obtained the drug registration certificate

The Company and the 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 received the Drug Registration Certificate (《藥品註冊證書》) of sevelamer carbonate tablets (碳酸司維拉姆片) (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: sevelamer carbonate tablets

Dosage form: Tablet

Specifications: 0.8g

Drug Category: Prescription Drugs

Registered classification: Class IV Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Drug registration (Domestic production)

Reception Number: CYHS2101173Guo

Drug approval number: Guoyao Zhunzi (《國藥准字》) H20233203

Notification number: 2023S00248

Approval Conclusion: According to the Drug Administration Law of the People's Republic of China and relevant provisions, after examination, the product meets the relevant requirements of drug registration, registration is approved and a drug registration certificate is issued. Quality standards, instructions, labels and manufacturing processes shall be carried out as attached. Drug manufacturers shall meet the requirements of the quality control standards for drug production before they can manufacture and sell drugs.

II. Other relevant information

In May 2021, Xinhua Pharmaceutical submitted to the Center for Drug Evaluation of the State Drug Administration (藥品審評中心) for the registration of sevelamer carbonate tablets. In February 2023, Xinhua Pharmaceutical obtained the Drug Registration Certificate(《藥品註冊證書》), and the review conclusion was approved for registration.

The original researcher of sevelamer carbonate tablets is Sanofi Genzyme. And sevelamer carbonate tablets has been listed and widely used in more than 40 countries including the United States, Japan, Canada and Europe. The original research was approved to enter China in June 2013. At present, there are only two companies listed for production in China, including original research and import.

Sevelamer carbonate tablets are used to control hyperphosphatemia in adult patients with chronic kidney disease (CKD) undergoing dialysis treatment, and belongs to the category B variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2020)”(《國家基本醫療保險、工傷保險和生育保險藥品目錄(2020年)》). According to relevant statistics, the global sales volume of sevelamer carbonate preparation in 2020 exceeded US \$ 700 million, and the terminal sales volume in Chinese public medical institutions exceeded RMB 500 million in 2021.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's sevelamer carbonate tablets has obtained the Drug Registration Certificate in February 2023, which will help the Company to open up new market areas and create new profit growth points.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest rationally and pay attention to investment risks.

By Order of the Board
**Shandong Xinhua Pharmaceutical Company
Limited**

27 February 2023