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 Febuxostat Tablets Having Obtained the Drug Registration Certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 11 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

11 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.: 2024-60

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Febuxostat Tablets 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.

A wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as the "**Company**"), Shandong Zibo Xincat Pharmaceutical Company Limited(hereinafter referred to as "**Xincat Pharmaceutical**"), has recently received the Drug Registration Certificate (药品注册证书) approved and issued by the National Medical Products Administration in connection with its febuxostat tablets (hereinafter referred to as the "**Product**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Febuxostat tablets
Dosage form:	Tablets
Specifications:	20mg
Drug category:	Prescription drugs
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Registration category:	Class 4 chemicals
Approval number:	CYHS2301652
Original drug approval number:	Guoyao Zhunzi (《国药准字》) H20249271
Certificate number:	2024S02658
Review Conclusion:	In accordance with *the Drug Administration Law of the People's Republic of China*（中华人民共和国药品管理法）and applicable regulation, upon review, the Product conforms to applicable requirements for drug registration, and approval is granted with the issuance of the drug registration. The standard of quality, product instruction, labelling as well as the production processes 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 June 2023, Xincat Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) concerning marketing of febuxostat tablets for domestic production and the application was accepted. In November 2024, Xincat Pharmaceutical obtained the Drug Registration Certificate (药品注册证书) with the review conclusion was that the registration was approved

and the Drug Registration Certificate was to be issued.

As a derivative of 2- arylthiazole, febuxostat is a xanthine oxidase inhibitor which can reduce serum uric acid concentration by inhibiting uric acid synthesis and is suitable for long-term treatment of hyperuricemia in goutpatients. Febuxostat is highly selective and its effect is stronger than that of Allopurinol. It is mainly metabolized by the liver and does not rely on renal excretion and is safe and effective for patients with mild to moderate renal dysfunction, with minimal side effects and definite therapeutic effects.

Febuxostat tablets belongs to category B variety under the "National Essential Medicines List" and "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)"(国家基本医疗保险、工伤保险和生育保险药品目录(2023年)). According to relevant data, sales volume of febuxostat tablets in public medical institutions in China was approximately RMB 777 million in 2023.

III. Impact on the Company and risk warning

The obtaining by Xincat Pharmaceutical in November 2024 of approval from the National Medical Products Administration in connection with its febuxostat tablets (20 mg) is beneficial to enriching the product line of the Company and enhancing its core competitiveness.

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

11 November 2024