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 Apixaban tablets obtaining the drug registration certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 18 October 2023. The English version of the said announcement is set out below for reference. If there is any inconsistency between the English version and the Chinese version of the announcement, the Chinese version shall prevail.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited
He Tongqing
Chairman

18 October 2023, Zibo, PRC

As at the date of this announcement, the board of directors of the Company 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

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-42

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Apixaban tablets obtaining 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 statement or material omission.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has received the Drug Registration Certificate（药品注册证书）issued by the National Medical Products Administration of the People's Republic of China in connection with the approval of its apixaban tablets (阿哌沙班片) (2.5mg) (hereinafter referred to as, the "**Product**"). In connection therewith, we heeby disclose as follows:

(i) Basic information

Drug name:	Apixaban tablets
Dosage form:	Tablet
Specification:	2.5mg
Drug category:	Prescription drugs
Registration category:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Permission for launch of drug
Approval number:	CYHS2200263
Drug approval number:	Guoyao Zhunzi (国药准字) H20234292
Notification number:	2023S01572
Review conclusion:	According to the Medicinal Product 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 conforms to applicable requirements for drug registration and the drug registration certificate has been issued. The standard of quality, product instructions and labelling as well as the production process 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 January 2022, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for registration and approval for launch of the drug, apixaban tablets, and the application was accepted. In October 2023, Xinhua Pharmaceutical obtained the Drug Registration Certificate (药品注册证书) after the review concluded that, upon examination, the drug meets all applicable requirements for registration, and hence, the registration was approved and drug registration certificate may be issued.

Apixaban tablets are oral anticoagulants for preventing venous thromboembolism events (VTE) in adult patients undergoing hip or knee joint replacement surgery. It was jointly developed by Bristol-Myers Squibb and Pfizer EEIG and launched in the European Union in May 2011. Subsequently, it entered the China market in January 2013 and entered its medical insurance catalog in 2017. Apixaban is a reversible, highly selective direct Xa inhibitor and a novel oral anticoagulant drug. Compared with vitamin K inhibitors such as warfarin, apixaban is comparatively safe and well tolerated, effectively reducing incidence of stroke and systemic embolism without increasing risks of bleeding. According to relevant data, global sales volume of Apixaban related preparations in 2021 was USD 21.259 billion. In 2022, the sales of apixaban tablets in urban public hospitals in China reached RMB 47.55 million.

(iii) Impact on the Company and risk warning

The obtaining of the Drug Registration Certificate by Xinhua Pharmaceutical concerning its apixaban tablets in October 2023 means that the drug is deemed to have passed necessary evaluation concerning quality and efficacy for production. This will enable the Company to expand its product offering to include the Product and may be conductive to new profit growth streams.

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

18 October 2023