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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 rabeprazole sodium enteric-coated tablets passing the generics consistency evaluation" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 13 June 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

13 June 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

Independent Non-executive Directors:

Mr. Pan Guangcheng

Mr. Zhu Jianwei

Mr. Lo Wah Wai

Mr. Ling Peixue

Non-executive Directors:

Mr. Cong Kechun

Mr. Xu Lie

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Rabeprazole Sodium Enteric-coated Tablets passing the generics consistency evaluation

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 recently received the Notice of Approval of Supplementary Drug Application (《药品补充申请批准通知书》) from the National Medical Products Administration in relation to the approval of Rabeprazole Sodium Enteric-coated Tablets (雷贝拉唑钠肠溶片) (hereinafter referred to as the "**Product**"), which has passed the "Consistency of Quality and Efficacy Evaluation for Generic Drugs" (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug Name: Rabeprazole Sodium Enteric-coated Tablets

Dosage form: Tablets

Specifications: 10mg

Drug Category: Prescription Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Consistency of Quality and Efficacy Evaluation for Generic Drugs

Acceptance Number: CYHB2250436

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20080683

Notification number: 2023B02977

Approval Conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In July 2022, Xinhua Pharmaceutical submitted registration materials for the consistency of quality and efficacy evaluation for generic drugs of Rabepazole Sodium Enteric-coated Tablets to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) and was accepted. In June 2023, the Company was granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that the Company has passed the consistency of quality and efficacy evaluation for generic drugs.

Rabepazole sodium was developed by Nippon Eisai Corporation and was first marketed in Japan in 1997. In 2003, domestic varieties were successively approved for listing.

Rabepazole sodium is a third-generation proton pump inhibitor used for the treatment of gastric ulcers, duodenal ulcers, anastomotic ulcers, reflux esophagitis, and Zollinger Ellison syndrome. It is also used to assist in eradicating *Helicobacter pylori* in patients with gastric or duodenal ulcers. Rabepazole sodium enteric-coated tablets belongs to the category B variety of the “National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2021 Edition)” (《国家基本医疗保险、工伤保险和生育保险药品目录(2021年)》). According to relevant data, the sales of rabepazole in urban public hospitals in China reached RMB 3.33 billion in 2022, of which the sales of oral dosage forms reached RMB 2.21 billion.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's rabepazole sodium enteric-coated tablets (specifications: 10mg) has passed the consistency of quality and efficacy evaluation for generic drugs in June 2023, which will help further enhance the Product's market competitiveness.

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

13 June 2023