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 esomeprazole magnesium having obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 2 September 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

2 September 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 Announcement No.: 2024-39

Shandong Xinhua Pharmaceutical Company Limited

Announcement on esomeprazole magnesium having obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs

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 Notification of Approval of Marketing Application for Chemical Substance Drugs (化学原料药上市申请批准通知书) in connection with its esomeprazole magnesium (hereinafter referred to as the "**Product**") which was approved and issued by the National Medical Products Administration ("**NMPA**"). Relevant information is now announced as follows:

I. Basic information

Drug name:	Esomeprazole magnesium
Dosage form:	Active Pharmaceutical Ingredients
Registration classification:	Chemical drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application natter:	Application for the Listing of Domestic Production of Chemical Raw Materials
Reception number:	CYHS2360181
Registration number:	Y20220001327
Notification number:	2024YS00904
Review conclusion:	According to the Pharmaceutical 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 is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation.

II. Other relevant information

In February 2023, Xinhua Pharmaceutical submitted an application for the registration of esomeprazole magnesium (i.e. the Product) to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) and such application was accepted. In September 2024, Xinhua Pharmaceutical obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

The Product is available both domestically and internationally, with formulations including enteric-coated tablets, enteric-coated capsules and enteric-coated dry suspension. The Product was first developed by the

AstraZeneca AB and its original formulation was approved for marketing in Sweden in March 2000 under the trade name, Nexium. It was later approved for import into China in October 2002 (under the trade name, Nexium), and subsequently approved for localization on 9 December 2004. AstraZeneca AB is a licensed manufacturer of reference preparations as published by the National Medical Products Administration.

Esomeprazole magnesium is used for the treatment of gastroesophageal reflux disease (GERD), including the treatment of reflux esophagitis, long-term treatment for patients with cured esophagitis to prevent the recurrence, symptom control of GERD; may be combined with appropriate antibacterial therapy to eradicate Helicobacter pylori; and used for patients who require continuous nonsteroidal anti-inflammatory drug (NSAID) treatment.

The Product is a proton pump inhibitor used to treat peptic ulcer disease and gastroesophageal reflux disease. Its formulation belong to the Class B varieties under the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2024)".

According to the statistics of relevant databases, the global sales of esomeprazole magnesium-related preparations in 2023 amount to about 3.164 billion United States dollars, with consumption of about 424 tons of active pharmaceutical ingredients.

III. Impact on the Company and risk warning

The approval of the Product indicates that this active pharmaceutical ingredientshas met the relevant national drug evaluation technical standards and has been approved for use in domestic formulations. It will further enrich the Company's product line for treating stomach diseases and enhance 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

2 September 2024