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 Cefixime Capsules Passing the Generics Consistency Evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 4 December 2023, 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

4 December 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

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-50

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Cefixime Capsules Passing the Generics Consistency Evaluation

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 Zibo Xinda Pharmaceutical Company Limited (hereinafter referred to as "**Xinda Pharmaceutical**"), a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as 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 of the People's Republic of China in relation to the approval of its cefixime capsules (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: Cefixime capsules

Dosage form: Capsules

Specification: 0.1g(calculate by $C_{16}H_{15}N_5O_7S_2$)

Drug category: Prescription drugs

Registration category: Chemicals

Applicant: Shandong Zibo Xinda Pharmaceutical Company Limited

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

Approval number: CYHB2250675

Original drug approval number: Guoyao Zhunzi (《国药准字》)H20070310

Notification number: 2023B06034

Review conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In November 2022, Xinda Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for registration concerning the consistency of quality and efficacy evaluation for the generic drug, cefixime capsules, and the application was accepted. In December 2023, we were issued the Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that we have passed the consistency of quality and efficacy evaluation regarding this generic drug.

Cefixime capsules are suitable for acute bronchitis, pneumonia, secondary infections of chronic respiratory infections, cystitis, pyelonephritis, gonococcal urethritis, cholecystitis, cholangitis, otitis media, sinusitis, scarlet fever caused by Streptococcus (excluding Enterococcus), Pneumococcus, Neisseria gonorrhoeae, Streptococcus subtilis, Escherichia coli, Klebsiella pneumoniae, Salmonella, Proteus, and Haemophilus

influenzae, among others that are sensitive to Cefixime.

Cefixime capsules are third-generation oral cephalosporins, which were originally developed by Fujisawa Pharmaceutical Co., Ltd. (now known as Astellas Pharmaceutical Co., Ltd.) in Japan. The marketed dosage forms include capsule (50mg and 100mg specifications) and fine granules (50mg specifications), with the trade name "Cefspan". Cefixime capsules belong to category B variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2022)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2022 年)》). According to relevant data, sales of Cefixime in public hospitals in Chinese cities reached RMB 1.05 billion in 2022, with capsule sales amount reaching RMB 290 million in monetary terms.

III. Impact on the Company and risk warning

Xinda Pharmaceutical's Cefixime capsules have passed the consistency of quality and efficacy evaluation for generic drugs in December 2023, which will help further enhance the Product's market competitiveness and support the implementation of the Company's large R&D strategy.

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

4 December 2023