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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 drugs of wholly-owned subsidiary passing the generics consistency evaluation” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 20 September 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

20 September 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

Non-executive Directors:

Mr. Cong Kechun
Mr. Xu Lie

Shandong Xinhua Pharmaceutical Company Limited**Announcement on drugs of wholly-owned subsidiary 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.

Xinhua Pharmaceutical (Gaomi) Co., Ltd. (hereinafter referred to as “**Gaomi**”), a wholly-owned subsidiary of the Company, has recently received the Notice of Approval of Supplementary Drug Application (《药品补充申请批准通知书》) issued by the National Medical Products Administration in relation to the approval of Clarithromycin Granules (克拉霉素颗粒) (0.125g) (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). The Company hereby announces the relevant information as follows:

I. Basic information

Drug Name: Clarithromycin granules

Dosage form: Granules

Specifications: 0.125g/5ml

Drug Category: Prescription drugs

Registration category: Chemicals

Applicant: Xinhua Pharmaceutical (Gaomi) Co., Ltd.

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

Approval Number: CYHB2250278

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20010616

Notification number: 2023B04585

Approval Conclusion: Upon review, the drug passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In May 2022, Gaomi submitted application materials for consistency of quality and efficacy evaluation concerning the generic drug, clarithromycin granules, to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) and the application was accepted. In September 2023, Gaomi was granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that the drug had passed the consistency of quality and efficacy evaluation for generic drugs. At present, Gaomi is the first company where the said drug has passed the consistency of quality and efficacy evaluation for generic drugs.

Clarithromycin granules are suitable for the following infections caused by clarithromycin-susceptible bacteria: Nasopharyngeal infections: tonsillitis, pharyngitis, sinusitis; Lower respiratory tract infection: acute

bronchitis, acute attack of chronic bronchitis and pneumonia; Skin and soft tissue infection: pustulosis, erysipelas, folliculitis, furuncle and wound infection; urethritis and cervicitis caused by acute otitis media, mycoplasma pneumonia, chlamydia trachomatis. The drug is also used for the treatment of Legionella infection, or in combination with other drugs for the treatment of mycobacterium avium infection and helicobacter pylori infection.

Clarithromycin granules is a Category B drug under 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, the sales of clarithromycin in urban public hospitals in China reached RMB 842 million in 2022.

III. Impact on the Company and risk warning

Gaomi's clarithromycin granules (specifications: 0.125g) 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) in September 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 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**

20 September 2023