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 escitalopram oxalate tablets(10mg) having obtained the drug registration certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 22 May 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

22 May 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 Annoucement No.: 2024-27

Shandong Xinhua Pharmaceutical Company Limited

Announcement on escitalopram oxalate tablets(10mg) having obtained 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 statements or material omissions.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the Drug Registration Certificate（药品注册证书）of escitalopram oxalate tablets (10mg) (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

Drug name: Escitalopram oxalate tablets

Dosage form: Tablets

Specifications: 10mg (according to $C_{20}H_{21}FN_2O$)

Drug category: Prescription drugs

Registered classification: Class 4 chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application matter: Drug Registration (Domestic production)

Case number: CYHS2200872

Drug approval number: GuoyaozhunziH20243682

Certificate number: 2024S00801

Review conclusion: In accordance with the Pharmaceutical 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 the relevant requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, instructions, labels, and production process 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 June 2022, Xinhua Pharmaceutical submitted the application materials to the Center for Drug Evaluation of

the State Drug Administration (药品审评中心) for the marketing of escitalopram oxalate tablets for domestic production and the application was accepted. In May 2024, Xinhua Pharmaceutical obtained the Drug Registration Certificate(《药品注册证书》), and the review conclusion was approved for production.

Escitalopram oxalate tablets is a single dextrorotatory optical isomer of racemic citalopram, a bicyclic hydrogenated phthalide derivative, used to treat depression. It is used to treat panic disorder with or without agoraphobia. Compared to similar antidepressants, escitalopram oxalate tablets has better efficacy and acceptability, and is a first-line drug for the treatment of depression.

Escitalopram oxalate tablets is a category A variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2023 年)》). According to relevant data, the terminal sales of escitalopram oxalate in Chinese public medical institutions in 2022 was about RMB1.88 billion.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's escitalopram oxalate tablets (10mg) has obtained the Drug Registration Certificate in May 2024, which is beneficial for enriching the neurological product line, and enhancing the market competitiveness of the Product.

It is hereby announced that 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

22 May 2024