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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 alogliptin benzoate tablets obtaining the drug registration certificate" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 11 August 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*

11 August 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 Alogliptin Benzoate Tablets Obtaining the Drug Registration Certificate

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 received the Drug Registration Certificate (《药品注册证书》) of alogliptin benzoate tablets (苯甲酸阿格列汀片) (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: Alogliptin Benzoate Tablets

Dosage form: Tablet

Specifications: 25mg、12.5mg

Drug Category: Prescription Drugs

Registered classification: Class 4 chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Drug registration (Domestic production)

Reception Number: CYHS2200419Guo、CYHS2200420Guo

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20234021、H20234022

Notification number:2023S01252、2023S01253

Approval 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 relevant regulations, the Product conforms to the relevant requirements of drug registration upon examination. As such, the drug registration certificate will be issued.

#### II. Other relevant information

In March 2022, Xinhua Pharmaceutical submitted the registration application materials for the marketing of alogliptin benzoate tablets for domestic production to the Center for Drug Evaluation of the State Drug Administration (the “CDE”) (药品审评中心) and was accepted. In August 2023, the Company obtained the Drug Registration Certificate (《药品注册证书》), which concluded that the registration was approved.

The Product is suitable for the treatment of type 2 diabetes. Single drug treatment: As an auxiliary treatment for diet control and exercise, the Product is used to improve blood sugar control in patients with type 2 diabetes. Use in combination with Metformin hydrochloride: When Metformin hydrochloride alone cannot effectively control blood sugar, the Product can be used in combination with Metformin hydrochloride to improve blood sugar control in patients with type 2 diabetes on the basis of diet and exercise.

The Product is used to treat type 2 diabetes, and it belongs to the category B variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2022 Edition)” (《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 statistics, the sales of alogliptin related preparations in the global was about \$696 million in 2021, the sales of alogliptin related preparations of public medical institutions in China was about RMB 270 million in 2022.

### **III. Impact on the Company and risk warning**

Xinhua Pharmaceutical's alogliptin benzoate tablet has obtained the Drug Registration Certificate in August 2023, which is conducive to enriching the Company's product series and providing more drug choices for diabetes patients.

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**

11 August 2023