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 obtaining notification of approval of marketing application for chemical raw material drugs" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 20 June 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 June 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

Mr. Ling Peixue

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-31

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Alogliptin benzoate obtaining notification of approval of marketing application for chemical raw material drugs

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 recently received the Notice of Approval of Marketing Application for Chemical Raw Material Drugs（《化学原料药上市申请批准通知书》） of alogliptin benzoate (hereinafter referred to as the "**Product**") issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

API Name: Alogliptin benzoate

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Application for lauching domestic production of chemical API

Acceptance Number: CYHS2160633

Registration Number: Y20210001145

Notification Number: 2023YS00358

Approval Conclusion: According to the Drug Administration Law of the People's Republic of China, after examination, the Product meets the relevant provisions of generic drug approval, and the production of the Product is approved. Quality standards, packaging labels and production processes shall be carried out as attached.

II. Other relevant information

In December 2021, the Company submitted the registration materials for the marketing application for the domestic production of Alogliptin benzoate as chemical raw materials to the Center for Drug Evaluation of the State Drug Administration (the "**CDE**") (药品审评中心) and was accepted. The Company received a supplementary research notice from the CDE in September 2022, and the Company completed the supplementary research work and submitted materials in February 2023. In June 2023, the Company obtained the Notification of Approval of Marketing Application for Chemical Raw Material Drugs《化学原料药上市申请批准通知书》,and the review concluded that the registration was approved.

The original research company of the Product is Takeda Pharmaceutical Company Limited, which was launched in Japan in 2010. In 2013, it was approved by the FDA (included as a reference formulation in the FDA Orange Peel Book) and approved for import domestically in the same year. The Product is suitable for the treatment of type II diabetes. Single drug treatment: As an auxiliary treatment for diet control and exercise, the Product is used to improve glycaemic control in patients with type II diabetes. Use in combination with Metformin hydrochloride: When Metformin hydrochloride alone cannot effectively control blood glucose, the Product can be used in combination with Metformin hydrochloride to improve blood glucose control in patients with type II diabetes on the basis of diet and exercise. The therapeutic effect is desirable and has good clinical application prospects.

According to relevant database statistics, the global sales of Alogliptin benzoate preparations will be about 696 million USD in 2021, and the consumption of raw medicine will be about 20 tons.

III. Impact on the Company and risk warning

The approval of the above products will further enrich the Company's product line and has a certain impact on the Company's future performance improvement.

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

20 June 2023