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**") will publish the "Announcement on Saxagliptin and Metformin Hydrochloride Sustained-release Tablets of subsidiary having obtained the Drug Registration Certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 5 March 2026. 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 March 2026, Zibo, the People's Republic of China

As at the date of this announcement, the board of directors of the Company 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

Shandong Xinhua Pharmaceutical Company Limited
Announcement on Saxagliptin and Metformin Hydrochloride Sustained-release Tablets of subsidiary 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 Zibo Xincat Pharmaceutical Company Limited (hereinafter referred to as, "**Xincat Pharmaceutical**"), a wholly-owned subsidiary of Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as, the "**Company**") , has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I), (III) (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:	Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I)、(III)
Dosage form:	Tablets
Specifications:	Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I): Each tablet contains 5mg of saxagliptin and 1000mg of hydrochloric acid metformin. Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (III): Each tablet contains 2.5mg of saxagliptin and 1000mg of hydrochloric acid metformin.
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Zibo Xincat Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2401958、CYHS2401959
Drug approval number:	National Medicine Zhunzi (国药准字) H20263398、H20263445
Notification number:	2026S00469、2026S00534
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 with the applicable requirements of drug registration, the drug registration is approved, and the *Drug Registration Certificate* has been issued. The standard of quality, product instructions, labels as well as production processes concerning the Product 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 2024, Xincat Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I), (III) and the application materials were accepted. Xincat Pharmaceutical obtained the *Drug Registration Certificate* recently, and the review conclusion was that the Product shall be approved for registration.

The Product, when used in combination with diet and exercise therapy, is suitable for improving the blood sugar control of adult patients with type 2 diabetes who are being treated with saxagliptin and metformin. The Product is not for use in patients with type 1 diabetes or diabetic ketoacidosis.

The Product is listed in the "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)" as a Category B product. According to relevant statistics, the sales of Saxagliptin and Metformin Hydrochloride Sustained-release Tablets in China's public medical institutions amounted to approximately RMB 419 million in 2024.

III. Impact on the Company and risk warning

Xincat Pharmaceutical's obtaining of approval in connection with its application concerning UrsodSaxagliptin and Metformin Hydrochloride Sustained-release Tablets (I), (III) recently is conducive to enriching the Company's hypoglycemic preparation series and enhancing its comprehensive 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
4 March 2026