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 Benserazide Hydrochloride having obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 9 May 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

8 May 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. 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 Pharmaceutical Announcement No.: 2026-26

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Benserazide Hydrochloride having obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs

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 *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书) in connection with its Benserazide Hydrochloride (hereinafter referred to as the "**Product**") which was approved and issued by the National Medical Products Administration ("**NMPA**"). Relevant information is now announced as follows:

I. Basic information

API name:	Benserazide Hydrochloride
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for the Marketing Authorisation of Domestically Produced Chemical Substance Drugs
Reception number:	CYHS2460791
Registration number:	Y20240000681
Notification number:	2026YS00408
Review 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 applicable regulation, upon review, the Product conforms to applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation.

II. Other relevant information

In September 2024, Xinhua Pharmaceutical submitted an application for the registration of Benserazide Hydrochloride (i.e. the Product) to the Center for Drug Evaluation of the National Medical Products Administration (CDE) and such application was accepted. In May 2026, Xinhua Pharmaceutical obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书), and the review conclusion was to approve the production of the Product.

Benserazide Hydrochloride is a peripheral decarboxylase inhibitor, which is combined with levodopa to make a compound preparation "dopa and benserazide". There are two dosage forms of dopa and benserazide approved by the State Food and Drug Administration: levodopa and benserazide hydrochloride tablets and levodopa and benserazide hydrochloride capsules. Levodopa and benserazide hydrochloride tablets are used for the treatment of Parkinson's disease, symptomatic Parkinsonism (post-encephalitis, arteriosclerotic, or toxic), but not drug-induced parkinsonism. Levodopa and benserazide hydrochloride capsules are used for the

treatment of Parkinson's disease and Parkinsonism.

The preparation of the Product is listed as a Category A product in the "National Drug Catalogue for Basic Medical Insurance, Work Related-Injury Insurance, and Maternity Insurance (2025)". According to relevant statistics, the sales of Benserazide Hydrochloride related preparations in China's public medical institutions amounted to approximately RMB 1.4 billion in 2024.

III. Impact on the Company and risk warning

Xinhua Pharmaceuticals' obtaining of Notification of Approval of Marketing Application for Chemical Substance Drugs in connection with Benserazide Hydrochloride in May 2026 will facilitate the Company's exploration of new market areas and enhance its core 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

8 May 2026