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 Levocarnitine Oral Solution having obtained Drug Registration Certificate*" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 21 September2026. 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

18 September 2026 Zibo, PRC 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 Director:

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 Levocarnitine Oral Solution having obtained 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 "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the *Drug Registration Certificate* (药品注册证书) in connection with its Levocarnitine Oral Solution (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:	Levocarnitine Oral Solution
Dosage form:	Oral solution
Specifications:	10ml:1g
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2404213
Drug approval number:	National Medicine Zhunzi (国药准字) H20266018
Certificate number:	2026S03468
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 regulations, 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 December 2024, Xinhua Pharmaceutical submitted application materials to the *Center for Drug Evaluation of the National Medical Products Administration* (药品审评中心) (CDE) concerning the marketing of Levocarnitine Oral Solution, and the application materials were accepted. In September 2026, Xinhua Pharmaceutical obtained the *Drug Registration Certificate*, and the review conclusion was that the Product shall be approved for registration.

The Product is used for the treatment of primary systemic carnitine deficiency. In reported cases, clinical manifestations have included recurrent Reye-like encephalopathy, hypoketogenic hypoglycemia, and/or cardiomyopathy. Associated symptoms include skeletal muscle hypotonia, muscle weakness, and failure to grow / thrive. Primary carnitine deficiency is diagnosed on the basis of low carnitine levels in the patient's serum, red blood cells and/or tissues, together with the absence of any primary defect in fatty acid or organic acid oxidation (see the section on Clinical Pharmacology). In some patients, particularly those presenting with cardiomyopathy, carnitine supplementation can rapidly relief the signs and symptoms of the disease. In addition to carnitine, supportive treatment and other therapeutic measures should be provided according to the patient's condition. The Product is also indicated for the short-term and long-term treatment of secondary carnitine deficiency due to inborn errors of metabolism.

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 Levocarnitine Oral Solution in China's public medical institutions amounted to approximately RMB400 million in 2025.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's obtaining of *Drug Registration Certificate* in connection with Levocarnitine Oral Solution in September 2026 will further enrich the oral metabolic modulator product pipeline of the Company and enhance its market 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
18 September 2026