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 citicoline sodium injection(4ml:0.5g) having passed the generics consistency evaluation" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 31 May 2024. 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

31 May 2024, 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. Xu Lie
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 Phramaceutical Annoucement No.: 2024-31

Shandong Xinhua Pharmaceutical Company Limited

Announcement on citicoline sodium injection(4ml:0.5g) having passed the generics consistency evaluation

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 Notice of Approval of Supplementary Drug Application from the National Medical Products Administration (《药品补充申请批准通知书》) that its citicoline sodium injection (hereinafter referred to as the "**Product**") increased by 4ml: 0.5g specification was approved and has passed the "Consistency of Quality and Efficacy Evaluation for Generic Drugs" (仿制药质量和疗效一致性评价). Relevant information is now announced as follows:

I. Basic information

Drug name:	Citicoline sodium injection
Dosage form:	Injection
Specifications:	4ml:0.5g(Calculated by $C_{14}H_{26}N_4O_{11}P_2$)
Drug category:	Prescription drugs
Registration ccategory:	Chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Increase specifications and apply for consistency evaluation of generic drug quality and efficacy
Case number:	CYHB2350259
Drug approval number:	GuoyaozhunziH20247114
Notification number:	2024B02418
Review conclusion:	After review, the supplementary application for the addition of 4ml: 0.5g specification of the Product was approved. The Product has passed the consistency of quality and efficacy evaluation for generic drugs.

II. Other relevant information

In March 2023, Xinhua Pharmaceutical submitted registration application materials in connection with the consistency of quality and efficacy evaluation for generic drugs of citicoline sodium injection (4ml:0.5g) to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) and the application was accepted. In May 2024, the Company was granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that the Product had passed the consistency of quality and

efficacy evaluation for generic drugs, and it was agreed to the specification 4ml: 0.5g may be added to the Product.

Citicoline sodium injection was developed by Ferrer Internacional S.A. and is suitable for acute craniocerebral trauma and disorders of consciousness after brain surgery. This Product belongs to category B variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)"(《国家基本医疗保险、工伤保险和生育保险药品目录(2023 年)》). According to relevant data, in 2023, the sales volume of citicoline sodium in Chinese urban public medical institution in 2023 reached RMB 1.628 billion, of which the sales volume of injection reached RMB 510 million.

III. Impact on the Company and risk warning

The passing of quality and efficacy consistency evaluation by Xinhua Pharmaceutical's citicoline sodium injection (4ml:0.5g) approved in May 2024 is conducive to the Product acquiring market share and enhancing 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 rationally and pay attention to investment risks.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited

31 May 2024