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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 Co., Ltd. (the "**Company**") has published the "Announcement on piracetam injection passing the generics consistency evaluation" on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 15 February 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

17 February 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

Shandong Xinhua Pharmaceutical Company Limited**Announcement on piracetam injection passing the generics consistency evaluation**

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 Supplementary Drug Application (《药品补充申请批准通知书》) from the National Medical Products Administration in relation to the approval of piracetam injection (吡拉西坦注射液) (hereinafter referred to as the "**Product**"), which 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: piracetam injection

Dosage form: Injection

Specifications: 5ml:1g

Drug Category: Prescription Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Consistency of Quality and Efficacy Evaluation for Generic Drugs

Reception Number: CYHB2250009

Original drug approval number: Guoyao Zhunzi (《国药准字》) H37023217

Notification number: 2023B00527

Approval Conclusion: Passed the consistency of quality and efficacy evaluation for generic drugs

II. Other relevant information

In January 2022, Xinhua Pharmaceutical submitted to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) for the registration of piracetam injection. In February 2023, Xinhua Pharmaceutical obtained the Notice of Approval of Supplementary Drug Application, and the review conclusion was that the consistency of quality and efficacy evaluation for generic drugs was passed. In February 2023, we were granted a Supplemental Drug Application Approval Notice (《药品补充申请批准通知书》), which concluded that we had passed the consistency of quality and efficacy evaluation for generic drugs.

The original researcher of piracetam injection is UCB Pharma, and piracetam injection is marketed in the European Union including Germany, Belgium, and Turkey. It is an original research product that has not been imported.

Piracetam injection is suitable for memory loss and for mild to moderate brain dysfunction caused by acute and chronic cerebrovascular diseases, brain trauma, various toxic encephalopathy, etc. It can also be used for children with mental retardation. Piracetam injection belongs to the category B variety of the “National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2020)”(《国家基本医疗保险、工伤保险和生育保险药品目录(2020年)》). According to relevant statistics, the sales of piracetam in urban public hospitals in China have grown continuously for the past three years, reaching RMB1.58 billion in 2021.

III. Impact on the Company and risk warning

Xinhua Pharmaceutical's piracetam injection has passed the consistency of quality and efficacy evaluation for generic drugs in February 2023, which will help further enhance the Product's market competitiveness.

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**

15 February 2023