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 obtaining Approval Notice for Supplementary Drug Application and other relevant information（《药品补充申请批准通知书》）" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 25 April 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

25 April 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

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-23

Shandong Xinhua Pharmaceutical Company Limited

Announcement on obtaining Approval Notice for Supplementary Drug Application and other relevant information

Shandong Xinhua Pharmaceutical Company Limited (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.

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 ambroxol hydrochloride oral solution (盐酸氨溴索口服溶液) (hereinafter referred to as the "**Product**"), and the application for transfer of marketing authorisation holder ("**MAH**") was approved. Relevant information is now announced as follows:

I. Basic information

Drug Name: Ambroxol Hydrochloride Oral Solution

Dosage form: Oral Solution

Specifications: 100ml:0.3g

Drug Category: Over-the-Counter Drugs

Registered classification: Chemicals

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Supplementary Application (change of MAH)

Acceptance Number: CYHB2300599

Original drug approval number: Guoyao Zhunzi (《国药准字》) H20233006

Notice number: 2023B01854

Approval Conclusion: Pursuant to the Drug Administration Law of the People's Republic of China(《中华人民共和国药品管理法》) and relevant regulations, it has been found that the transfer application of the MAH of the Product meets the relevant requirements relating to change management after the drug is launched. Therefore, the Notice of Approval of Supplementary Drug Application（《药品补充申请批准通知书》） has been issued.

II. Other relevant information

(1)In May 2022, the Company and Jiangsu Wangao Pharmaceutical Company Limited (hereinafter referred to as "**Wangao Pharmaceutical**") signed a technology transfer contract. The contract stipulates that Wangao Pharmaceutical will transfer the MAH and all related technical rights (including but not limited to interests in product production technology, sales, market promotion, etc.) of the proposed ambroxol hydrochloride oral solution to the Company in one go, with a total technology transfer fee of RMB 8.5 million. The Company will pay the relevant transfer fee to Wangao Pharmaceutical in stages according to the agreement.

Pursuant to the Rules Governing the listing of Stock on Shenzhen Stock Exchange (《深圳证券交易所股票上市规则》) and the Articles of Association (《公司章程》), the transaction is not required to be submitted to the Company's board of directors and shareholders' meeting for approval.

The transaction does not constitute a related party transaction, nor does it constitute a significant asset restructuring as stipulated in the Measures for Administration of Material Assets Reorganization of Listed Companies(《上市公司重大资产重组管理办法》).

(2)In August 2021, Wangao Pharmaceutical submitted an application to the State Drug Administration for the marketing registration of Ambroxol Hydrochloride Oral Solution (100ml:0.3g), which was accepted by the State Drug Administration. In March 2023, the Company submitted an application to the State Drug Administration to change the MAH of Aminobroxol Hydrochloride Oral Solution (100ml :0.3g) and the application was accepted, and in April 2023, the Company obtained the Notice of Approval of the Supplemental Drug Application.

(3)Ambroxol hydrochloride oral solution can increase the secretion of mucous glands in the respiratory tract and reduce the secretion of mucous gland, thereby reducing the viscosity of sputum, while promoting the secretion of pulmonary surfactant, increasing the movement of bronchial cilia to make sputum easier to cough up, which is suitable for the phlegm caused by acute and chronic bronchitis that is thick and difficult to cough up.

Ambroxol hydrochloride was developed and marketed by Dr. Karl Thomae GmbH in Germany. Currently,

various dosage forms such as tablets, injections, oral solutions, and inhalation solutions are available for sale both domestically and internationally.

According to relevant data, the sales of ambroxol in urban public hospitals in China were approximately RMB 3 billion in 2021.

III. Impact on the Company and risk warning

The supplementary application for Ambroxol Hydrochloride Oral Solution(100ml:0.3g) passed the review of the National Medical Products Administration in April 2023, and the Company has become the MAH of the Product. The launch of the Product has enriched the Company's product line and is conducive to the implementation of the Company's major research and development strategy.

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

25 April 2023