**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 the progress of clinical trials of OAB-14 dry suspension" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 22 August 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*

22 August 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 Announcement No.: 2024-38

**Shandong Xinhua Pharmaceutical Company Limited**
**Announcement on the progress of clinical trials of OAB-14 dry suspension**

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 completed the Phase I clinical trial study in connection with its OAB-14 dry suspension (hereinafter referred to as, the "**Product**") for the treatment of mild to moderate Alzheimer's disease, in which the human body's tolerance and the pharmacokinetic characteristics of the new drug has been observed through preliminary clinical pharmacology and human safety evaluations, and with expected goals having been achieved, it is currently proposed to proceed to the Phase II drug clinical research stage.

## I. Basic information

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|---|---|
| Drug name: | OAB-14 |
| Dosage form: | Dry suspension |
| Specification: | 0.2g/0.625g |
| Treatment of indications: | Mild to moderate Alzheimer's disease |
| Registration classification: | Chemical medicine class 1 |
| Applicant: | Shandong Xinhua Pharmaceutical Company Limited |
| Manufacturer: | Shandong Zibo Xincat Pharmaceutical Co., Ltd. (a wholly-owned subsidiary of the Company) |

## II. Research status of the drug

OAB-14 is a Class 1 innovative chemical drug with independent intellectual property rights that has beeen jointly developed by Xinhua Pharmaceutical and Shenyang Pharmaceutical University for the treatment of mild to moderate Alzheimer's disease (AD).

OAB-14 is a novel anti-AD drug candidate with a novel mechanism of action, mainly related to the clearance of Aβ in the brain, as well as mechanisms involving central anti-inflammatory, antioxidation and inhibition of neuronal apoptosis. OAB-14 can significantly reduce the deposition of beta amyloid protein in the brain, reduce the excessive phosphorylation of Tau protein, and protect the structure and function of cerebral cortex, hippocampal neurons and synapses. At present, the Product has completed Phase I clinical trial research and is preparing to enter Phase II drug clinical research stage.

In January 2023, the Company obtained the approval and issuance of the OAB-14 "Drug Clinical Trial Approval Notice" from the National Medical Products Administration. For details, please refer to the announcement on CNINFO(巨潮資訊網) dated 13 January 2023.

The Phase I clinical study has achieved the expected goals through preliminary clinical pharmacology and human safety evaluations which observed the human body's tolerance and pharmacokinetic characteristics of the new drug. Under the prescribed experimental conditions, our OAB-14 dry suspension was shown to be sound in terms of safety and tolerability for healthy adult subjects.

It is expected that the Phase II clinical trial of our OAB-14 dry suspension will be initated within the year, and it would involve multi-center, randomized, double-blind, placebo-controlled evaluations under the second phase clinical study for the evaluation of the safety, tolerance, efficacy and pharmacokinetic characteristics of OAB-14 dry suspension for the treatment of Alzheimer's disease.

## III. Risk warning

According to the applicable laws and regulations concerning drug registration in China, the Product must complete clinical research and be reviewed and approved by the National Medical Products Administration before it can be produced and marketed.

The research and development of pharmaceutical products is a lengthy process involving multiple steps (including the conducting of clinical trials and the making of registration applications prior to stage of industrialised production), and may be subject to various uncertainties arising from such factors as technical or regulatory approval. The competitive landscape for similar products in the future may also evolve. The Company will pay close attention to the actual progress of drug registration applications and fulfill the obligation of information disclosure in a timely manner.

Investors are advised to invest sensibly and pay attention to investment risks.

By Order of the Board
**Shandong Xinhua Pharmaceutical Company Limited**

22 August 2024