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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 Company Limited (the “**Company**”) shall publish an “Announcement on the Completion of Enrollment of the First Patient in China for Phase II Clinical Trials of OAB-14 Dry Suspension” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 20 June 2025. 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*

19 June 2025, Zibo, PRC

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 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

**Shandong Xinhua Pharmaceutical Company Limited****Announcement on the Completion of Enrollment of the First Patient in China for Phase II Clinical Trials of OAB-14 Dry Suspension**

The Company and the board of directors of the Company 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 enrollment of the first patient in China for Phase II clinical trial of OAB-14 dry suspension for the treatment of mild to moderate Alzheimer's disease. Relevant information is now announced as follows:

**I. Basic information**

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

**II. Research situation of the drug**

As announced by the Company under the "Announcement on the Progress of Clinical Trial of OAB-14 Dry Suspension" on CNINFO (巨潮資訊網) on 23 August 2024 (announcement number 2024-38), the OAB-14 dry suspension was safely administered and well tolerated in healthy adult subjects with no obvious indications of accumulation in the body following multiple number of administrations under existing experimental conditions.

The Xuanwu Hospital of Capital Medical University jointly participated in the Phase II drug clinical trial of OAB-14 dry suspension with multiple centers across the country, and the enrolment of the first patient in China for Phase II clinical trial of OAB-14 was completed on 19 June 2025.

**III. Other information about the drug**

OAB-14 is a new chemical drug with innovative structure and independent intellectual property rights that was jointly developed by Xinhua Pharmaceutical and Shenyang Pharmaceutical University. It belongs to Class 1 innovative drugs, and the suggested indication is for treatment of mild to moderate Alzheimer's disease (AD).

The Company commenced a non-clinical study in 2019, the results of which showed that OAB-14 could significantly improve the learning memory and social activities of APP/PS1 transgenic AD mice. The anti-AD effect of OAB-14 is mainly related to the elimination of A $\beta$  in the brain, as well as the mechanism of anti-

inflammatory, anti-oxidation, and inhibition of neuronal apoptosis in central facilities. OAB-14 can significantly reduce the deposition of amyloid  $\beta$ -protein in the brain, reduce the hyperphosphorylation of Tau protein, and protect the structure and function of neurons and synapses in the cerebral cortex and hippocampus. No abnormal histopathological changes related to the tested substance were found in safety pharmacology and toxicology studies.

#### **IV. Risk warning**

According to applicable laws and regulations concerning drug registration in China, drugs 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 (involving the conducting of clinical trials) may be a lengthy process involving multiple steps from the time of registration of applications to industrialised production, and may be subject to various uncertainties arising from technical aspects, regulatory approval hurdles and other factors. The competitive landscape for similar products in the future may also evolve. The Company will pay close attention to the actual progress of drug research and development and fulfill the obligation of information disclosure in a timely manner.

Investors are advised to invest rationally with particular attention to investment risks.

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

19 June 2025