

[For Immediate Release]



中國抗體製藥有限公司
SinoMab BioScience Limited
(Incorporated in Hong Kong with limited liability)
(Stock Code: 3681)

SinoMab Submits Another IND Application for Flagship Product SM03 (Suciraslimab) for the Treatment of Alzheimer’s Disease, Which was Accepted by NMPA CDE

(15 November 2023 – Hong Kong) A Hong Kong-based biopharmaceutical Company dedicated to the research, development, manufacturing and commercialisation of therapeutics for the treatment of immunological diseases - **SinoMab BioScience Limited** (Stock Code: 3681.HK, “**SinoMab**” or the “**Company**”), is pleased to announce that on 14 November 2023, an Investigational New Drug application (“IND”), for Mild Cognitive Impairment (“MCI”) or Mild Dementia due to Alzheimer’s Disease (“AD”) for Suciraslimab has been filed with and accepted by the Center for Drug Evaluation (the “CDE”) of the National Medical Products Administration of China (the “NMPA”). If the application is successfully approved, the Company will conduct comprehensive clinical development program in China which leads to indication for treatment of early phase symptomatic AD, including MCI or Mild Dementia due to AD.

As the Company’s flagship product, Suciraslimab is the Company’s self-developed product and is a first-in-class anti-CD22 monoclonal antibody for the treatment of rheumatoid arthritis (“RA”), and potentially other diseases such as systemic lupus erythematosus (SLE), non-Hodgkin’s lymphoma (NHL), Sjogren’s syndrome (SS) as well as Alzheimer’s Disease (AD). It is clinically proven to be effective in treating autoimmune diseases and controlling inflammation, with excellent long-term safety and rare serious adverse reactions, and has the potential to become a new type of therapeutic drug for Alzheimer’s disease. This IND application is mainly for Alzheimer’s disease, and the Company will initiate the Phase I clinical study in China upon approval of the present IND.

Alzheimer’s disease, as the most common type of dementia, is a neurodegenerative disease with insidious onset and progressive development. In particular, MCI is an important stage of intervention in Alzheimer’s disease, which may slow down the occurrence of Alzheimer’s disease, and it is precisely the main application stage of IND application for Suciraslimab. Meanwhile, Suciraslimab’s mechanism of action could potentially resolve the safety issue currently faced by A β antagonist immunotherapeutic drugs. Suciraslimab, upon binding to CD22, promotes the clearance of β -amyloid and simultaneously suppresses

neuroinflammation, offering a therapeutic advantage over other approved products which clear β -amyloid at the expense of neuroinflammation. With this unique mechanism of action, Suciraslimab could potentially reduce the risk of serious adverse reactions commonly associated with anti- β -amyloid treatments and mitigate adverse reactions associated with amyloid-related imaging abnormalities (ARIA).

According to the mechanism of action, Suciraslimab does not directly antagonise $A\beta$, but rather achieves the clearance of $A\beta$ deposits by modulating microglial cells, the primary phagocytes responsible for clearing $A\beta$ in the brain. The microglia surface resembles CD22 and its elevated level of expression is associated with Alzheimer's disease. According to the article published in the Journal of "Nature", it is shown that the microglia can engulf and clear $A\beta$ and targeting CD22 can significantly accelerate this journey. The Company's internal studies have shown that Suciraslimab has a dual effect that other $A\beta$ antagonist monoclonal antibodies do not possess. On the one hand, it promotes the phagocytosis and clearance of $A\beta$ deposits by microglial cells, thereby alleviating the neurotoxicity caused by these deposits. On the other hand, Suciraslimab has anti-inflammatory effects and can act within the central nervous system to suppress brain inflammation. More importantly, as Suciraslimab does not directly bind to $A\beta$, it can effectively avoid the activation of inflammatory vectors caused by $A\beta$ -IgG immune compound, reduce the permeability of blood vessels caused by inflammatory reactions, thereby effectively preventing amyloid-related imaging abnormalities (ARIA) and its associated severe adverse reactions. The groundbreaking dual mechanism of action of Suciraslimab has the potential to efficiently clear $A\beta$ under safer conditions, improve symptoms of Alzheimer's disease, and reduce the safety risks that current $A\beta$ antagonist immunotherapies struggle to address. It holds promise as the next-generation drug for treating Alzheimer's disease.

With the acceleration of the ageing population, the number of Alzheimer's disease-based dementia patients continues to increase, seriously threatens the health and life quality of the elderly, and there is an urgent need to develop effective treatments. According to the report by **Chen Zhu, the Vice Chairman of the Standing Committee of the 13th National People's Congress, the President of the Red Cross Society of China and the member of the Chinese Academy of Sciences**, presented at the "2023 China Brain Health Conference", there are 10 million Alzheimer's disease patients in China and the number is expected to continue growing. According to "China's Alzheimer's Disease Report 2022", Alzheimer's disease currently incurs an annual economic burden of RMB160 million and ranks as the fifth leading cause of death among Chinese residents. The "China Alzheimer's Disease Report 2021" also indicates that the prevalence and mortality rate of Alzheimer's disease and other dementia in China are slightly higher than the global average, further demonstrating the vast market potential driven by patient demand. Globally, there are more than 55 million dementia patients and this number

is projected to increase to nearly 139 million by 2050. Over 10 million new cases of dementia are diagnosed worldwide each year. The Company believes that the research and development of Suciraslimab for Alzheimer's disease targeting early symptoms can provide new possibilities for effective treatment for Alzheimer's disease patients and has great market potential.

The Company is also committed to advancing multiple indications studies for Suciraslimab. The unblinding and initial statistical analysis of Phase III clinical trial of Suciraslimab for rheumatoid arthritis (RA) has been completed while the primary endpoint was achieved on 26 April 2023. The relevant biologics license application for Suciraslimab in the treatment of RA was accepted by the NMPA in September 2023 and is currently under technical review. A Phase III extension study on RA is also ongoing in China.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of the Company, said, "The increasing number of Alzheimer's disease cases poses a heavy burden on numerous families. Developing targeted new drugs as early as possible to intervene in the disease during the early stages is a key strategy for alleviating Alzheimer's disease. The acceptance of the new drug application for Suciraslimab for the treatment of Alzheimer's disease will help it exert its unique mechanism of action and therapeutic advantages to help slow down the progression of Alzheimer's disease, improving patients' quality of life and alleviating the socioeconomic burden of the disease. The Company is confident in the significant clinical trial and commercial development prospects of Suciraslimab as a new drug. We believe that the new drug can provide effective and safe treatments for the Alzheimer's disease, and is expected to benefit more Chinese patients in the future. In addition, the Company will continue to promote product research and development and accelerate commercialisation progress, striving to improve drug accessibility. We adhere to the concept of independent innovation and constantly work towards becoming a leading global biopharmaceutical company in developing innovative drugs to fulfill unmet medical needs.

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About SinoMab BioScience Limited

SinoMab BioScience Limited is dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases. The R&D headquarters is located in Hong Kong and the production base is located in mainland China. The Company's flagship product Suciraslimab is a potential global first-in-target mAb against CD22 for the treatment of rheumatoid arthritis (RA) and has completed the Phase III clinical trial for rheumatoid arthritis in China, which has been recognized as one of the significant special projects of Significant New Drugs Development of the Twelfth Five-Year Plan Period and the Thirteenth Five-Year Plan Period. In addition, the Company possesses other potential first-in-target and first-in-class drug candidates, some of which are already in clinical stage,

with their indications covering rheumatoid arthritis (RA), Alzheimer's disease, systemic lupus erythematosus (SLE), pemphigus (PV), multiple sclerosis (MS), neuromyelitis optica spectrum disorder (NMOSD), non-Hodgkin's lymphoma (NHL), asthma, and other diseases with major unmet clinical needs.

This press release is issued by **Financial PR (HK) Limited** on behalf of **SinoMab BioScience Limited**. For further information, please contact:

Financial PR (HK) Limited

Contact: Ms. Chloe Chiu / Ms. Serena Zhang / Ms. Willa Xue / Ms. Romy Hong

Email: sinomab@financialpr.hk

Tel: (852) 2610 0846

Fax: (852) 2610 0842