

[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’s IND Application of SM17 has once again Received Approval from NMPA Clinical Development Program for the Treatment of AD to be Initiated Shortly**

(11 September 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 the Investigational New Drug application (“IND”), for the treatment of patients with atopic dermatitis (“AD”) for the Company’s First-in-Class (FIC) therapeutic product SM17, was approved by the National Medical Products Administration of China (**the “NMPA”**) on 8 September 2023. The Company plans to initiate a Phase I clinical study in China in the fourth quarter of this year to investigate the safety profile of SM17 in Chinese population and to initiate the clinical development program of SM17 for the treatment of allergic diseases.

SM17 is a novel, First-in-Class (FIC), humanized, IgG4-k monoclonal antibody which is capable of modulating Type II allergic reaction by targeting the receptor of a critical “alarmin” molecule interleukin 25 (IL-25). SM17 could suppress Th2 immune responses by binding to IL-25 receptor (also known as IL-17RB) on Type 2 Innate Lymphoid cells (ILC2s) and Type 2 helper T (Th2) cells, to block a cascade of responses induced by IL-25 and suppress the release of the downstream Th2 cytokines such as IL-4, IL-5 and IL-13.

IL-25 is a critical cytokine classified as “alarmin”, which has shown to be implicated in the pathogenesis of autoimmune and inflammatory skin diseases, such as AD. Patients with AD also have an increasing all-cause mortality rate and disease-specific mortality rate in the following diseases, which include infections, respiratory diseases, gastrointestinal diseases and oncologic diseases. Current approved therapies for AD, including biologics, can significantly improve eczema area and severity index and patient’s quality of life. However, there are still some patients who show irresponsiveness to those approved therapies. AD lacks universally effective treatment methods and there is an urgent need to fill the market gap with suitable medications.

AD, as a common chronic disease, is showing an increasing prevalence in China, indicating a wide market space for potential treatments. According to Frost & Sullivan, there were approximately 65.7 million AD patients in China in 2019 and is expected to grow to 81.7 million in 2030, and 30% of which will be moderate-to-severe patients. China’s AD medicine market was US\$600 million in 2019, and is expected to grow to US\$1.5 billion in 2024, and is expected to increase to US\$4.3 billion in 2030, indicating a considerable market size. We believe

that therapies targeting upstream of the Th2 inflammatory cytokine pathway, such as IL-25 receptor, will have broad effects on skin inflammation, implicating a great potential for SM17 as a differentiating, safer and more effective products for the treatment of atopic dermatitis.

The Company actively promoted the indication research of SM17, laying a foundation for subsequent proof of concept and commercialization. Currently, a Phase I study for SM17 conducted in the US is near completion, with the Last Subject Last Visit (LPLV) scheduled later this month (September 2023). As of the date of this announcement, no drug-related serious adverse event has been reported, suggesting the product is well tolerated in human and shows a very good safety profile. The IND application of SM17 for the treatment of asthma diseases was approved by the NMPA on 11 August 2023 and its Phase I clinical study in China will also be initiated shortly.

**Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of the Company**, said, “As the number of AD patients continues to grow, its unmet need in China is becoming increasingly recognized. The IND application of SM17 for AD has been approved by the NMPA, which fully reflects the recognition of the differentiated advantages of SM17 in the field of AD and has a bright future. We will initiate a Phase I clinical study and a clinical development plan of SM17 for the treatment of allergic diseases in China soon, striving to provide more effective medical solutions for Chinese patients. Currently, SM17 has obtained IND approvals from the NMPA for the treatment of asthma and AD, while our Phase I study for SM17 conducted in the US is near completion. This strategic layout would assist us to move forward our business development into the international market. In the future, we will also continue to make in-depth strategies in the field of immunological diseases, leverage our scientific research strengths, continuously expand the population of indications, provide breakthrough scientific treatment solutions for the research of immunological diseases and more safe and effective treatment options for the patients, so as to consolidate the Company’s leading market position, and aim to become a global leader in the innovative treatment of immunological diseases.”

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#### **About SinoMab BioScience Limited**

SinoMab BioScience Limited is dedicated to the research, development, manufacturing and commercialisation 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 SM03 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:

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