

[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 Announces IND Application of SM17 for the Treatment of Asthma was Accepted by NMPA CDE

Accelerating Domestic Clinical Trials and Targeting the Blue Ocean of Asthma Drugs

(22 May, 2023 - Hong Kong) A Hong Kong-based biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases - **SinoMab BioScience Limited (Stock Code: 3681.HK, "SinoMab" or the "Company")**, is pleased to announce that an Investigational New Drug ("IND") application for SM17 (a humanised anti-IL-17RB monoclonal antibody for injection) for the treatment of Asthma has been filed with and accepted by the Center for Drug Evaluation ("CDE") of the National Medical Products Administration of China ("NMPA") on 19 May. The present IND submission, once granted, will enable the Company to conduct comprehensive clinical development program in China which leads to indication for treatment of asthma.

SM17 is a humanized, IgG4-k monoclonal antibody targeting IL-17RB, which is a global first-in-class monoclonal antibody drug targeting IL17BR with the potential for treating asthma, atopic dermatitis, idiopathic pulmonary fibrosis and other immunological disorders. This IND application is mainly for the treatment of asthma, and upon approval of the present IND, the Company plans to initiate a Phase I clinical study in China to bridge between Chinese(Asian) and American(Caucasian/Black) populations, as well as to investigate the safety profile of SM17 in Chinese population.

As early as March 2022, SM17's IND Application for the treatment of asthma was approved by the U.S. Food and Drug Administration ("FDA"), and the first healthy subject had been successfully dosed in a Phase I clinical First-in-Human(FIH) clinical trial in June 2022. As of today, none of the subjects reported a serious adverse event. We are in full steam ahead to accelerate the progress of our clinical study. According to our current progress, we expect the Phase I clinical study can be completed by the end of this year, six months ahead of the original anticipated completion date.

SM17 could suppress Th2 immune responses by binding to IL-17RB on Type 2 Innate Lymphoid cells (ILC2s), blocking a cascade of responses induced by interleukin-25 (IL-25). IL-25 is a critical cytokine classified as "alarmin", which has shown to be implicated in the pathogenesis of airway viral responses and allergic disease,

such as asthma. Patients with severe, uncontrolled asthma are at a risk of recurrent asthma exacerbations and hospitalizations, and uncontrolled severe asthma is associated with increased mortality/morbidity, diminished quality of life and increased health expenditures.

As one of the global pandemic, asthma has huge urgent and unmet medical needs, and the pharmaceutical market has a broad space. According to the Frost & Sullivan Report, the number of asthma patients worldwide is gradually increasing and expected to reach 800 million in 2024 and further increase to approximately 860 million in 2030. The number of asthma patients in China grew faster than the global growth rate and is expected to reach 70.4 million in 2024 and further increase to 78.1 million in 2030. In terms of market size, the global asthma product market is expected to reach US \$38.5 billion in 2024 and US \$50 billion by 2030. The asthma product market in China is expected to reach US \$5.6 billion by 2024 and US \$9.7 billion by 2030, of which the market size of moderate-to-severe asthma applicable for biologics will reach US \$6.6 billion. Current approved therapies for severe asthma, including biologics, can reduce asthma annual exacerbations to a certain extent. However, there is still an unmet medical need for additional effective therapies, particularly for patients who do not respond to current treatments. The Company expected that targeting upstream mediators of the Th2 inflammatory cascade, such as IL-17RB, will have a broad effect on airway inflammation and improve disease conditions. The Company believes SM17 may have great potential to satisfy unmet medical needs in asthma treatment.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab said that, “The number of asthma patients worldwide has increased year by year, and the existing therapies have not fully met the medical needs, and there is still a huge gap in effective treatment of severe asthma. As the world's first humanized IgG4-κ monoclonal antibody targeting IL-17RB, SM17 has made satisfactory progress in clinical research under the active promotion of the Company. The acceptance of IND Application for SM17 not only accelerated the Company’s clinical development project for the treatment of asthma indications in China, but also demonstrated the high efficiency of our new drug development. The Company is confident in the prospects of clinical trial and commercial development of the new drug of SM17, and will continue to explore its safety and efficacy. It is expected that this new treatment option will benefit more Chinese patients in the future and bring a promising treatment for severe asthma patients. The Company will adhere to independent innovation, continue to promote the investigatory of new drugs, expand the population of indications, spare no effort to provide more effective treatment options for Chinese and global patients, aiming to become a global leader in innovative therapies for immunological diseases.”

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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 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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