

[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 that IND Application of SM17 for the Treatment of Asthma was Approved by NAMP ***Speeding up Domestic Clinical Trials***

(14 August 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 the Investigational New Drug (“IND”) application, for the treatment of patients with asthma for the Company’s First-in-Class (FIC) therapeutic product SM17, was approved by the National Medical Products Administration of China (the “NMPA”) on 11 August 2023. The Company plans to conduct a Phase I clinical study in China soon 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, 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, blocking a cascade of responses induced by IL-25, and suppressing 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 multiple airway viral responses and allergic diseases, such as asthma. Patients with severe, uncontrolled asthma are at risk of recurrent asthma exacerbations and hospitalizations, and uncontrolled severe asthma is associated with increased mortality and morbidity, diminished quality of life and increased health expenditures.

Meanwhile, the Company is also advancing the Phase I clinical study of SM17 in the U.S. at full speed. Based on the current progress, the Company expects to complete the Phase I clinical study by the end of this year, half a year ahead of the anticipated completion date. 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.

As a new pathway for asthma treatment, therapy targeting the upstream mediators of the Th2 inflammatory

cascade pathway, such as “alarmin”, is expected to have a broad effect on airway inflammation. This is expected to lead to more effective control of asthma symptoms and an improvement in disease conditions compared to existing therapies. This has also been validated in the clinical trial of SM17.

The potential first-in-target antibody of SM17 has demonstrated the potential efficacy for multiple indications, including asthma and IPF (Idiopathic Pulmonary Fibrosis). The above unique mechanism enables SM17 to cover more diversified indications, which can not only target indications with huge market size such as asthma and atopic dermatitis, but also treat diseases with high mortality rate such as IPF, and continuously expand its indication coverage. Compared with other currently approved therapeutic antibody drugs targeting ILC2s downstream pathway, SM17 has a differentiated advantage at the source.

As one of the global pandemics, asthma has caused social problems, with huge and urgent medical needs that cannot be ignored. The number of asthma patients worldwide is increasing year by year, and a large patient base is in urgent need of effective therapeutic drugs to alleviate unmet medical needs. According to the Frost & Sullivan Report, the number of asthma patients worldwide is expected to increase to approximately 860 million in 2030, of which the number of asthma patients in China will increase to 78.1 million which is higher than the global growth rate. The Company expects that targeting upstream mediators of the Th2 inflammatory cascade, such as the receptor for IL-25, will have a broad effect on airway inflammation, which is expected to provide a new therapeutic channel with efficacy and safety for asthma diseases and bring relief and treatment to asthma patients.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab said that: "SM17's IND application for the treatment of asthma has been approved three months after it was accepted by the NMPA, which demonstrates that the efficient execution of the Company's new drug R&D program is well recognized by the NMPA, and also fully reflects the huge potential of SM17 in unmet medical needs for asthma treatment. We are confident in the huge clinical development and commercialization prospects of SM17, and will accelerate the progress of clinical trials and strive to achieve commercial business as soon as possible in the future. At the same time, we continue to expand the scope of indications so that new treatment options can benefit more Chinese patients in the future. The Company will continue to focus on autoimmune diseases, and spare no effort to provide more effective treatment options for Chinese and global patients with abundant technical reserves and strong innovation capabilities."

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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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