[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 Phase III Clinical Trial of its Flagship Product SM03 (Suciraslimab) Achieved the Primary Endpoint for Rheumatoid Arthritis

(April 26, 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 Phase III clinical trial of SinoMab's flagship product SM03 (Suciraslimab) for rheumatoid arthritis (RA) in China (Study No.: SM03-RA-III) has completed unblinding and initial statistical analysis and achieved the primary endpoint, marking a significant step towards Suciraslimab's commercial launch.

Suciraslimab is a global first-in-target anti-CD22 monoclonal antibody for the treatment of rheumatoid arthritis, and it is also the first-in-class anti-CD22 naked monoclonal antibody that has completed phase III clinical trial and reached the primary endpoint. The Phase III clinical trial is a randomized, multi-centre, double-blind, placebo-controlled study to confirm the clinical efficacy and safety in patients with moderate-to-severe active RA who had an inadequate response to methotrexate (MTX). The primary endpoint of the phase III trial is to measure the percentage of participants with ACR 20 response at week 24. ACR20 is a composite measure for the assessment of rheumatoid arthritis improvement by the American College of Rheumatology, defined as a minimum 20% improvement in the number of tender and number of swollen joints compared to the patient's own baseline, and at least 20% improvement in three of the following five measurements: including three visual scoring scale (VAS, which refers to doctors' overall assessment of disease activity, patients' general assessment of disease activity, patients' assessment of pain conditions), the patient's health assessment questionnaire (HAQ-DI) and the level of acute phase reactant (blood sediment or C-reaction protein) tested by laboratories.

The Phase III study results showed that Suciraslimab was effective in suppressing disease activity and alleviating symptoms of active RA patients receiving MTX therapy. Relevant study result shall be published in academic journals and academic conferences.

As a self-developed global first-in-target and first-in-class product of the Company, Suciraslimab demonstrates

clinical efficacy for the treatment of RA and via the modulation of B cell activity, it has the potential for the treatment of other immunological diseases. By adopting a novel mechanism of action, which differentiates itself from the current treatments available in the market, Suciraslimab offers a new option for RA patients to obtain long-term treatment benefits, addressing the limitations of currently available treatments in terms of efficacy, safety, and in particular, deficiency in long-term post-drug resistance against mature RA targets. Currently, the overall scale of existing patients with autoimmune diseases in China is huge. According to "Rheumatoid Arthritis in China: A National Report of 2020" issued by the National Clinical Research Center for Dermatologic and Immunologic Diseases in October 2021, there are about 5 million RA patients in China. According to Frost & Sullivan, the RA therapeutics market in the PRC is expected to reach RMB28 billion by 2023 and RMB83.3 billion by 2030. The unmet medical needs of RA patients in China are huge, and the market size of RA is also in a high-speed expansion stage. SinoMab is expected to fully share the benefits of the rapid development of the domestic autoimmune market.

SinoMab has been focusing on the R&D of monoclonal antibody drugs in the field of autoimmune diseases for more than 20 years, with an existing product pipeline covering a plethora of immunological disorders. SinoMab is one of the few biopharmaceutical companies in China that has the ability to integrate R&D, production, and commercialization to realize the entire industrial chain. The significant progress achieved in the Phase III clinical trial marks another big step towards the commercialization of Suciraslimab. The Group will accelerate the commercialization of Suciraslimab and strive to submit the Biologics License Application (BLA) to the National Medical Products Administration (NMPA) in the third quarter of 2023 at its earliest, so as to achieve commercialization subsequently and consolidate the first-mover advantage in the first-in-target and first-in-class of new medicine. While bringing the gospel to RA patients as soon as possible, we will promote the Company's business development to a new level, and continue to move forward to the goal of becoming a leading global biopharmaceutical company for the development of novel drugs to fulfil unmet medical needs.

In addition to its flagship product, Suciraslimab, another of the Company's core products, SM17, has made satisfactory progresses. SM17 is a humanised anti-IL-17RB monoclonal antibody, a First-in-Class and First-in-Target therapeutic product with potentials for treating diseases of type 2 immune responses such as asthma, atopic dermatitis, and idiopathic pulmonary fibrosis. Preclinical studies had revealed that SM17 is able to control inflammatory airway diseases such as asthma at a relatively early stage and is expected to address an unmet medical need by benefiting a large number of patients with severe uncontrolled asthma. The first IND application for the treatment of asthma was approved by the U.S. Food and Drug Administration ("FDA") in March 2022 and the first healthy subject had been successfully dosed in a Phase I First-in-Human (FIH) clinical study in the U.S. in June 2022. As of 31 December 2022, 59 subjects were enrolled and no serious adverse events were reported. We plan to carry out a bridging study in China and file an IND application for the treatment of asthma in China with the Center for Drug Evaluation (CDE) of NMPA in the first half of this year.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab said that, "the market for therapeutics for autoimmune diseases is in a stage of rapid growth, in which the demand for rheumatoid arthritis treatment is high. However, there are limitations on the efficacy and safety of currently available drugs for RA treatment. Suciraslimab, the Company's flagship product, is the world's first CD22-targeted new drug that is expected to be approved for marketing for the treatment of rheumatoid arthritis. The Phase III clinical data readout has successfully reached the primary endpoint and further demonstrated the efficacy of the new drug. We would like to express our sincere gratitude to all researchers and subjects for their efforts in the smooth advancement of the clinical research of this project. As the first Hong Kong-based listed biopharmaceutical company, we are pleased Suciraslimab is destined to be our first drug to be commercially marketed. In the future, the Company will continue to make every effort to promote discovery research to identify novel targets and antibodies that address immunological diseases of unmet medical needs. The company will continue to strive to advance preclinical and clinical research for marketing approval, and achieve the goal of product commercialization in the shortest possible time. Realizing SinoMab's commitments to becoming a leader in the innovation of novel drugs to fulfill unmet medical needs while creating more value returns for the Company and its shareholders is of prime importance."

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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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