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

INSIDE INFORMATION
UPDATE ON THE BLA FOR SM03 (SUCIRASLIMAB) IN THE TREATMENT OF RHEUMATOID ARTHRITIS

This announcement is made by SinoMab BioScience Limited (中國抗體製藥有限公司) (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

Reference is made to the announcements of the Company dated 7 April 2020, 8 June 2020, 22 June 2020, 28 September 2020, 27 October 2020, 30 November 2021, 26 April 2023 and 5 September 2023 and 15 November 2023 in relation to the latest research and development progress of the Company's flagship product, SM03 (Suciraslimab).

As disclosed in the Company's announcements dated 26 April 2023 and 5 September 2023, Suciraslimab met the primary endpoint in a Phase III clinical study for the treatment of rheumatoid arthritis ("**RA**") in China and submitted a biologics license application ("**BLA**") application to the National Medical Products Administration (the "**NMPA**") of the People's Republic of China ("**PRC**").

Unblinded pivotal Phase III data demonstrated Suciraslimab's clear and significant therapeutic efficacy in rheumatoid arthritis patients. The primary endpoint (ACR20 response rate at Week 24 of the double-blind phase) achieved an approximately 50% response rate and showing statistically significant differences versus the control group. With long-term treatment, ACR20 response rates continued to improve over time and exceeded 65% at Week 52 and surpassed 70% through Week 104 of the extension period, with no new safety risks revealed. Based on the clinical data from the Phase III clinical study and extension study, Suciraslimab demonstrated good long-term efficacy and safety.

The board of directors of the Company (the "**Board**") today announces that, following recent communications with the Center for Drug Evaluation (CDE) of the NMPA, the Company has voluntarily withdrawn the BLA application for Suciraslimab in the treatment of RA in China. This decision was made following an internal assessment that confirmed the need to supplement evidence of early therapeutic benefits, a key regulatory consideration for marketing approval as explicitly highlighted by the CDE, to support BLA approval.

The Company remains confident of the approval of Suciraslimab for marketing in China. We believe that Suciraslimab, with its unique mechanism of action, can achieve long-term efficacy and safety in the treatment of autoimmune disease indications including rheumatoid arthritis and systemic lupus erythematosus by preferentially targeting and inhibiting autoreactive B cells. The Company has already initiated planning for new clinical development program for Suciraslimab in treating systemic lupus erythematosus.

Meanwhile, the Company's deep, broad and differentiated pipelines contain multiple clinical-stage and preclinical novel drug candidates, including but not limited to, two innovative drug under the clinical stage and four innovative drugs in the preclinical stage. We will continue to advance the R&D and clinical development of these pipelines, including further clinical study of SM17. The positive topline results of SM17 Phase 1b clinical trial were published on 7 April 2025.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to ultimately develop and market SM03 (Suciraslimab) successfully. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board
SinoMab BioScience Limited
Dr. Shui On LEUNG
Executive Director, Chairman and Chief Executive Officer

Hong Kong, 14 July 2025

As at the date of this announcement, the executive director of the Company is Dr. Shui On LEUNG, the non-executive directors of the Company are Dr. Haigang CHEN, Mr. Xun DONG, Ms. Xiaosu WANG and Dr. Jianmin ZHANG and the independent non-executive directors of the Company are Mr. George William Hunter CAUTHERLEY, Mr. Ping Cho Terence HON, Dr. Chi Ming LEE, Ms. Chi Sau Giselle LEE and Mr. Nan SHEN.