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SinoMab BioScience Limited

中國抗體製藥有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 3681)

VOLUNTARY ANNOUNCEMENT

BLA ACCEPTED BY THE NMPA FOR SM03 (SUCIRASLIMAB) IN THE TREATMENT OF RHEUMATOID ARTHRITIS

Reference is made to the announcements of SinoMab BioScience Limited (中國抗體製藥有限公司) (the “**Company**”) dated 7 April 2020, 8 June 2020, 22 June 2020, 28 September 2020, 27 October 2020, 30 November 2021 and 26 April 2023 in relation to the latest research and development progress of the Company’s flagship product, SM03 (Suciraslimab).

The board of directors (the “**Board**”) of the Company is pleased to announce that the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China (“**PRC**”) has accepted the biologics license application (“**BLA**”) for the Company’s flagship product, SM03 (Suciraslimab), in the treatment of rheumatoid arthritis (“**RA**”) (Acceptance No.: CXSS2300072). The application is the first market filing of the Company since its establishment. Suciraslimab is the Company’s self-developed product and is a global first-in-target anti-CD22 monoclonal antibody for the treatment of RA and other immunological diseases, it adopts a novel mechanism of action unique to SM03, which differentiates itself from the current treatments available in the market.

The unblinded Phase III data revealed that Suciraslimab met its primary end point and achieved significant clinical efficacy for patients suffering from active rheumatoid arthritis, after 24-week period of double blinded treatment. In a 26-week open-label extension period, we observed that the number of responders continued to increase. Subgroup analyses further identified patient population that responded favorably with Suciraslimab. The clinical results were in agreement with the mechanism of action of Suciraslimab, which suggests that Suciraslimab acts on the more upstream process by preferentially targeting and suppressing pathogenic (autoreactive) B cells via the conversion of CD22 from a cis-binding configuration to a trans-binding configuration. The mechanism of action also explains why a superior safety profile was observed with Suciraslimab, as the normal functions of other protective B cells are left unperturbed. Detailed results of the clinical data and analyses will be reported as publications in medical journals.

RA is an autoimmune disease that causes chronic inflammation of the joints and other areas of the body. The inflammation causes tissues that line the inside of joints to thicken, resulting in swelling and pain in and around the joints. There is no permanent cure for RA, and patients require long term care to treat the symptoms.

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. With the continuous improvement of the diagnosis and treatment rate of autoimmune diseases in China and the continuous progress of related medical technologies, the market size of RA in China is expected to expand rapidly. 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.

Cautionary Statement required by Rule 18A.05 of the Rules of Governing the Listing of Securities on the Stock Exchange: 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, 5 September 2023

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. Wenyi LIU, Ms. Jie LIU and Mr. Lei SHI, and the independent non-executive directors of the Company are Mr. George William Hunter CAUTHERLEY, Mr. Ping Cho Terence HON, Dr. Chi Ming LEE and Mr. Dylan Carlo TINKER.