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
POSITIVE TOPLINE RESULTS FROM PHASE 1B CLINICAL TRIAL OF SM17 IN CHINA FOR THE TREATMENT OF MODERATE-TO-SEVERE ATOPIC DERMATITIS

Percentage AD Patients treated with high-dose of SM17 achieving:

— *NRS-4 (>90% vs 0% in placebo)*

— *EASI75 (>70% vs 0% in placebo)*

— *IGA 0/1 (>40% vs 0% in placebo)*

Safety: No SAE, no drug-related AEs with grade 3 or above

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 16 February 2022, 14 March 2022, 15 June 2022, 22 May 2023, 12 June 2023, 14 August 2023, 11 September 2023, 27 November 2023 and 11 June 2024 in relation to the latest research and development progress of one of the Group's key products, SM17.

The board of directors (the "**Board**") of the Company is pleased to announce the positive topline results of its Phase 1b clinical trial of SM17 in China for the treatment of moderate-to-severe Atopic Dermatitis ("**AD**") with differentiating efficacies, especially on anti-pruritus effect.

The Phase 1b trial is a multi-centered, randomized, double-blinded, placebo-controlled study, aiming to study safety, tolerability and pharmacokinetics (PK) profiles of SM17, as well as to explore the preliminary efficacy of SM17 in moderate-to-severe AD patients. A total of 32 moderate-to-severe AD patients were enrolled in this Phase 1b study, and randomized as 3:3:2 to receive doses of either high dose of SM17 (600mg), low dose of SM17 (200mg) or placebo in a 12-week treatment period followed by a 4-week maintenance/ follow-up period. Primary endpoint is safety profile of SM17 as tolerability throughout 16-week period, incidence of treatment-emergent adverse events (TEAE), changes of vital signs and laboratory testing. Secondary endpoints include efficacy measures assessing improvement of the following parameters:

- Pruritus: PP-NRS (peak pruritus numeric rating scale, PP-NRS)
- Skin healing: EASI (eczema area and severity index), BSA (body surface area), SCORAD (SCORing Atopic Dermatitis), vIGA-AD (validated Investigator's Global Assessment for Atopic Dermatitis)
- AD patients' quality of life: DLQI (Dermatology Life Quality Index), POEM (Patient Oriented Eczema Measure)

Immunogenicity, pharmacokinetics (PK) and pharmacodynamics (PD) profiles of SM17 in AD patients were also evaluated in this study.

Study Results

Phase 1b POC data for SM17 treating patients with moderate-to-severe AD, achieving:

- **Safety (Primary Endpoint Met):** SM17 is well-tolerated in 16-week treatment and follow-up period, No serious adverse events (SAEs); no drug-related grade 3 or above adverse events (AEs) were reported. Safety findings were generally consistent with the safety profile of SM17 previously observed in US Phase 1 and China Phase 1a bridging study. The most frequent TEAE (incidence >10%) in SM17 groups were nasopharyngitis and urinary tract infection, but incidence rate difference to that of placebo was less than 5%.
- **Pruritus reduction-NRS-4 (Secondary endpoint):** 91.7% (11/12) patients in SM17 high dose group vs. 0.0% (0/8) patients in placebo group reached ≥4-point reduction from baseline at end of treatment (EOT) in weekly average PP-NRS scores — superior to anti-IL4R antibodies (historical data[1]: 35.9%~40.8%) and better than JAK inhibitors (historical data[2]: 42%~64%) or IL-31R inhibitor (historical data[3]: ~65%).
- **Skin clearance-EASI75 (Secondary endpoint):** 75.0% (9/12) patients in SM17 high dose group vs. 0.0% (0/8) patients in placebo group reached greater than 75% improvement in EASI score from baseline at EOT — superior to anti-IL4Ra antibodies (historical data[1]: 44.2~52.5%) and comparable to JAK inhibitors (historical data[2]: 60% ~80%).

[1] Dupixent@ Prescribing information, SOLO-1 & SOLO-2 studies
[2] RINVOQ@ Prescribing information, Measure Up 1 & Measure Up 2 studies
[3] Phase 2B randomized study of nemolizumab in adults with moderate-to-severe atopic dermatitis and severe pruritus. Silverberg, Jonathan I. et al. Journal of Allergy and Clinical Immunology, Volume 145, Issue 1, 173–182

- **Skin clearance-IGA 0/1 (Secondary endpoint):** 41.7% (5/12) patients in SM17 high dose group vs: 0.0% (0/8) in placebo group reached 0 or 1 and at least 2 points reduction from baseline in vIGA-AD at EOT — superior to anti-IL4R antibodies (historical data[1]: 36.1%~37.9%) and approaches that of JAK inhibitors (historical data[2]: 39~62%).

High dose of SM17 also achieved promising results, demonstrating obvious improvement from baseline in all other secondary endpoints, including skin healing effect (EASI50, EASI90, BSA, SCORAD) and patients' quality of life (DLQI). Low dose of SM17, albeit not as effective as the high dose group, also showed a dose-response trend in alleviating pruritus symptoms, as well as improvement in skin healing by comparing to placebo.

Detailed topline data will be published in academic journals/academic conferences.

About SM17

SM17 is a novel, First-in-Class (FIC), humanized, IgG4-κ 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 Type 2 helper T (Th2) immune responses by binding to IL-25 receptor (also known as IL-17RB) on Type 2 Innate Lymphoid cells (ILC2s) and Th2 cells, to block a cascade of responses induced by IL-25 and suppress 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 autoimmune and inflammatory skin diseases, such as AD. Patients with AD also have an increasing all-cause mortality rate and disease-specific mortality rate in the following diseases, which include infections, respiratory diseases, gastrointestinal diseases and oncologic diseases. Current approved therapies for AD, including biologics, can significantly improve eczema area and severity index and patient's quality of life. However, there is still an unmet medical need for patients showing irresponsiveness to those approved therapies.

The Company performed a first-in-human Phase 1 clinical trial (NCT05332834) in the US to evaluate the safety and tolerability of SM17 in healthy subjects. Clinical report obtained in the first quarter of 2024 revealed a good safety profile of SM17 with no drug-related serious adverse event reported. In May 2024, a Phase 1a bridging study was also completed in China and demonstrated that SM17 to have good tolerability and safety profile and comparable PK profile as in Caucasian population.

Study results of SM17 were published in various leading international journals. Preclinical work of SM17, demonstrating the therapeutic efficacy of SM17 is comparable to, and in some parameters even outperform than, that of JAK1 inhibitor in treating animals with AD, were published in *Allergy*, an official journal of the European Academy of Allergy and Clinical Immunology (EAACI), on 9 April 2024. Pre-clinical models and Phase 1 clinical study of SM17 on healthy participants, showing SM17's outstanding profile in terms of safety, tolerability, and pharmacokinetic in healthy participants, were also published in *Frontiers in Immunology*, on 9 December 2024.

[1] Dupixent@ Prescribing information, SOLO-1 & SOLO-2 studies
[2] RINVOQ@ Prescribing information, Measure Up 1 & Measure Up 2 studies

The Company believes that therapies targeting upstream of the Th2 inflammatory cytokine pathway, such as IL-25 receptor, will have broad effects on skin inflammation, implicating a great potential for SM17 as a differentiating, safer and more effective products for the treatment of AD.

The Company is in the process of preparing a Phase 2 clinical study in China.

Shareholders of the Company and potential investors should 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, 7 April 2025

As at the date of this announcement, the executive directors are Dr. Shui On LEUNG and Mr. Shanchun WANG, the non-executive directors are Dr. Haigang CHEN, Mr. Xun DONG, Ms. Xiaosu WANG and Dr. Jianmin ZHANG, and the independent non-executive directors are Mr. George William Hunter CAUTHERLEY, Mr. Ping Cho Terence HON, Dr. Chi Ming LEE and Mr. Dylan Carlo TINKER.