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
IND APPLICATION FOR SM17 ACCEPTED BY NMPA CDE

Reference is made to the previous announcements of SinoMab BioScience Limited (中國抗體製藥有限公司) (the "**Company**", together with its subsidiaries, the "**Group**") on 16 February 2022, 14 March 2022, 15 June 2022, 22 May 2023, 12 June 2023, 14 August 2023, 11 September 2023, 27 November 2023, 11 June 2024, 7 April 2025 and 14 October 2025 regarding the 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 that on 11 December 2025, an Investigational New Drug application ("**IND**"), for SM17 in the indication of Inflammatory Bowel Disease ("**IBD**") has been filed with and accepted by the Center for Drug Evaluation (the "**CDE**") of the National Medical Products Administration ("**NMPA**") of China.

Upon approval of this IND application, the Phase 1 clinical trial data in healthy volunteers that the Company has completed or is currently conducting may be leveraged to support the progression of the IBD indication directly to Phase 2 clinical development. This IND submission represents an important step toward expanding SM17's therapeutic scope beyond atopic dermatitis ("**AD**") to IBD, including Crohn's disease ("**CD**") and ulcerative colitis ("**UC**"), which are chronic, debilitating conditions with significant unmet medical needs.

SM17 is a novel, first-in-class humanized IgG4-κ monoclonal antibody designed to modulate Type II inflammatory responses by targeting the receptor of interleukin 25 (IL-25), an "alarmin" molecule central to Type 2 immunity. By binding to the IL-25 receptor (IL-17RB) on Type 2 innate lymphoid cells (ILC2s) and Th2 cells, SM17 blocks IL-25-induced signaling cascades and suppresses downstream cytokines including IL-4, IL-5, and IL-13. This mechanism positions SM17 as a promising candidate for UC, where IL-25 plays a pro-inflammatory role. Furthermore, SM17 offers potential benefits in CD through two complementary mechanisms: modulation of Th17-driven inflammation and an anti-fibrotic effect, which may help address complications such as strictures and fistulas. This multi-mechanistic profile differentiates SM17 from current single-pathway therapies and provides a novel option for patients with refractory or complex disease phenotypes.

IL-25 is a critical cytokine implicated in the pathogenesis of inflammatory bowel diseases, including CD and UC. These chronic inflammatory disorders of the digestive tract arise from a dysfunctional immune response to normally harmless commensal bacteria. Depending on the dominant T-helper cell subsets, these responses can be categorized into Th1-, Th2-, or Th17-driven pathways, each associated with distinct cytokine profiles. Patients with IBD suffer from symptoms such as severe diarrhea, abdominal pain, rectal bleeding and weight loss, often complicated by fistulas, strictures and colectomy in advanced stages. Beyond physical morbidity, the relapsing nature of IBD significantly impairs quality of life, with high rates of anxiety, depression and work productivity loss. The global annual cost of IBD management is estimated to exceed USD34 billion. Current therapies, including TNF blockers, anti-integrins, and IL-12/23 inhibitors, do not fully address the needs of 20–50% of patients due to primary non-response or secondary loss of response within 1–2 years, particularly in those with fistulizing CD or extensive luminal disease. This challenge is largely attributable to the significant heterogeneity of IBD pathological pathways, which makes single-cytokine targeting insufficient for all patient subsets, and is further compounded by the absence of anti-fibrotic activity in these therapies, allowing progressive tissue remodeling to continue in complicated cases. Long-term use also raises safety concerns, including increased risks of infection and malignancy.

Currently, SM17 is undergoing bridging clinical trials for dosage form conversion, which is expected to be completed as early as the end of February next year, and it is expected to enter Phase 2 clinical trials for AD by mid-2026.

The Company believes that expanding SM17's indication from AD to IBD represents a significant opportunity to address unmet medical needs in a disease area of substantial clinical and commercial importance.

The Company further believes that therapies targeting upstream of the Th2 inflammatory cytokine pathway, such as the IL-25 receptor, may have broad effects on skin inflammation, supporting SM17's potential as a differentiated, safer, and more effective product for the treatment of AD.

The Company will continue to update shareholders and potential investors on material progress in accordance with applicable regulatory requirements.

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

Hong Kong, 11 December 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.