

【For Immediate Release】



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

**SinoMab (03681.HK) Achieves Key Regulatory Milestone as NMPA Accepts IND Application
for SM17, a Novel IL-25 Receptor Antibody for Inflammatory Bowel Disease**

(11 December 2025 - Hong Kong) **SinoMab BioScience Limited** ("**SinoMab**" or the "**Company**", Stock code: 03681.HK), is pleased to announce 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. This milestone represents an important advancement in the development of SM17.

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.

According to the data of an independent market research institution, the global annual cost of IBD management is estimated to exceed USD 34 billion. In addition, 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.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab, comments: "The IND for SM17 in the indication of IBD is a great milestone of the development of this innovative drug. 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. In addition, SM17 has multi-mechanistic profile differentiating it from

current single-pathway therapies and provides a novel option for patients with refractory or complex disease phenotypes. At the same time, we further believe 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."

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 IBD, including CD and UC. These chronic inflammatory disorders of the digestive tract arise from 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.

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

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About SinoMab BioScience Limited

SinoMab BioScience Limited (Stock Code: 03681.HK) is a pioneer in the research and development of first-in-class and potential best-in-class therapeutic antibody drugs, focusing on autoimmune diseases, neurodegenerative diseases, and other debilitating diseases, committed to addressing unmet medical needs. SinoMab has consistently focused on developing therapeutic antibodies targeting novel targets and employing innovative mechanisms, aiming to achieve differentiated clinical outcomes in areas where existing therapies have shown limited efficacy. Its rich R&D pipeline includes: SM17, which has demonstrated exceptional anti-pruritic effects, skin clearance rates, and safety profiles in the treatment of AD, with potential applications in asthma and idiopathic pulmonary fibrosis (IPF); its flagship anti-CD22 antibody, Suciraslimab, which has been clinically validated for efficacy in rheumatoid arthritis (RA) and is currently undergoing clinical

evaluation for systemic lupus erythematosus (SLE) and Alzheimer's disease; another innovative anti-CGC (common gamma chain) monoclonal antibody, which is preparing to enter clinical studies for the treatment of alopecia areata and vitiligo; and a bispecific monoclonal antibody developed by SinoMab that simultaneously stimulates bone growth and inhibits bone loss for the treatment of osteoporosis. With breakthrough efficacy as its core pursuit, SinoMab continuously redefines patient care standards and maintains a leading position in the field of breakthrough therapies.

This press release is issued by Zhenzhuo Group on behalf of **SinoMab BioScience Limited**.

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