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

Breakthrough Phase 1b POC Results for SM17 in Atopic Dermatitis Potentially a First-and Best-in-Class Product, Combining Deep Pruritus Relief, Effective Skin Clearance, and a Well-tolerated Safety Profile

(9 April 2025 – Hong Kong) **SinoMab BioScience Limited (Stock Code: 3681.HK, "SinoMab" or the "Company")**, is pleased to announce our breakthrough topline results from the completed Phase 1b clinical study evaluating SM17, a novel investigational therapy targeting the IL-25 (IL-17E) receptor pathway in moderate to severe atopic dermatitis (AD). SM17 uniquely binds to the co-receptor for IL-25, a key alarmin, and blocks downstream signaling – disrupting the inflammatory cascade driven by IL-25 engagement.

SM17 Competitive Advantages:

- **First AD biologic with dual efficacy** --- first and the only AD biologic that could reach both NRS-4[1] and EASI-75[2] responder rate over 60%[3] simultaneously at end of treatment (EOT), comparing to marketed product.

- **Faster and deeper itch relief than anti-IL-4/13 agents**[4]--- onset of anti-pruritus effect as early as Week 2 (SM17) vs Week 4~6 (other agents), over 90% of patients achieved NRS-4 (SM17) vs 30~40% of patients (other agents) at EOT.

- **Safer than JAK inhibitors**[5] --- No serious adverse events (SAEs) nor drug related Grade 3 or above adverse events (AEs) reported， minimum risk of serious infections or major adverse cardiovascular events (MACE).

【1】NRS-4: a peak pruritus numeric rating scale (PP-NRS) weekly mean score with a ≥4-point reduction from baseline

【2】EASI-75: ⩾75% reduction from baseline in Eczema Area and Severity Index (EASI) score

【3】SM17 ph1b NRS-4 responder rate:91.7%, EASI-75 responder rate 75.0%

【4】Dupixent@ Prescribing information, SOLO-1 & SOLO-2 studies

【5】RINVOQ@ Prescribing information, Measure Up 1 & Measure Up 2 studies

This Phase1b study, which evaluated two doses level of SM17 (200mg and 600mg, respectively), met its primary endpoints manifested as the safety profiles in patients with moderate-to-severe AD by demonstrating that SM17 was well-tolerated with no serious adverse event (SAE) or treatment-related adverse events (TRAEs) with grade 3 or above. In terms of efficacy, this study met all the

secondary endpoints assessing pruritus, skin healing and AD patients' quality of life by demonstrating remarkable differences between SM17 treatment groups and placebo group.

This study was a 16-week, randomized, placebo-controlled, double-blind study to assess the tolerability, safety and efficacy of SM17 monotherapy in 32 adults with moderate-to-severe AD, most of whom were previously inadequate responder to topical corticosteroids (TCS). Patients with a history of biologic (Dupilumab) or systemic Janus kinase (JAK) inhibitor medication (Upadacitinib) were also enrolled in the study.

At week 12, 75.0% of patients（9 /12） in the higher dose group achieved ≥75% reduction from baseline in EASI-75, vs. 0.0% of patients in the placebo group, with difference of responder rate as 75.0%（95% CI：32.00~91.11）. In the lower dose group, 50.0% of patients (6/12) achieved EASI-75, a 50.0% difference vs. placebo (95%CI：9.27~74.62).

In the higher dose group, 41.7% of patients (5/12) achieved a validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD™) score of 0 (clear) or 1 (almost clear) with a ≥2-point reduction from baseline (vIGA-AD 0/1) at week 12, representing a 41.7% difference vs. placebo (95%CI: 2.28~68.05). In the lower dose group, 25.0% of patients (3/12) achieved this endpoint, a 25.0% difference vs. placebo (95%CI: -11.22~53.23).

It is particularly noteworthy that 91.7% of patients (11/12) in the higher dose group achieved a peak pruritus numeric rating scale (PP-NRS) weekly mean score with a ≥4-point reduction from baseline (NRS-4) at week 12, vs. 0.0% of patients in the placebo group. Even in the lower dose group, 66.7% of patients (8/12) achieved this endpoint, remarkably different to that of the placebo group.

With regard to the onset of action, SM17 showed obvious anti-pruritus effect as early as week 2 after the initial dose, in either the higher or the lower dose group. The altitude of improvement in pruritus for SM17 treatment groups increased alongside with dosing and reached a mean level of 68% and 57% reduction from baseline in PP-NRS score at week 12, for higher and lower dose groups, respectively, vs. 18% for placebo group. Improvement in pruritus was also maintained for both SM17 treatment groups until week 16, which was 6 weeks away from last dosing (week 10). Improvement in skin healing showed similar trends, with a mean level of 73% and 57% reduction from baseline in EASI score at week 12 for the 2 treatment groups，vs. a mean level of 42% reduction from baseline in placebo group.

In addition, this Phase 1b study also met the endpoint of EASI 50 and EASI 90 at week 12, as well as superior improvement comparing to placebo in other skin healing measures as SCORAD and AD body surface area (BSA), or patients' life quality questionnaire - Dermatology Life Quality Index (DLQI).

Major efficacy endpoints results were summarized in the table below.

Endpoints		SM17 Higher dose（N=12）	SM17 Lower dose（N=12）	Placebo （N=8）
EASI 50（%）	Week12	83.3	66.7	25.0
	Week16	91.7	58.3	25.0
EASI 75 (%)	Week12	75.0	50	0.0
	Week16	41.7	41.7	0.0
EASI 90 (%)	Week12	41.7	16.7	0.0
	Week16	41.7	41.7	0.0
IGA 0/1 (%)	Week12	41.7	25.0	0.0
	Week16	33.3	41.7	0.0
NRS-4（%）	Week12	91.7	66.7	0.0
	Week16	75.0	58.3	25.0

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 TEAEs (≥10%) in SM17 groups were nasopharyngitis and urinary tract infection，with the overall incidence rate difference between the treatment group and the placebo group being less than 5%.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab, said, "SM17 has the potential to become a first- and best-in-class therapy for atopic dermatitis (AD), a market where a single transformative therapy can achieve multibillion-dollar (US) annual revenue. Pruritus is the primary concern for most of the patients with moderate-to-severe AD，and scratching behavior triggered by itch is likely the key driving factor in recurrent chronic inflammatory cycle in AD. With a favorable safety profile and skin clearance comparable to the most effective existing therapies, SM17 also delivers exceptional efficacy in itch relief – the most critical unmet need for patients. By addressing these key gaps in current treatment options, SM17 is positioned to redefine the standard of care for this debilitating condition. We are accelerating our clinical programs and actively pursuing partnerships to maximize its global impact. Next, we anticipate initiating Phase 2 trials in adults with moderate-to-severe AD. Notably, preclinical studies have shown promising results for SM17 in treating other Type 2 allergic diseases such as asthma, Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) and idiopathic pulmonary fibrosis (IPF). These findings suggest that SM17 could become a versatile therapeutic for a range of Th2-driven diseases, extending its potential beyond AD as a first- and best-in-class option."

About Atopic Dermatitis Market

Atopic dermatitis (AD) is a chronic inflammatory skin disease with a complex pathogenesis involving genetic predisposition, skin barrier dysfunction, immune system dysregulation, and environmental factors. The immunological characteristics of AD are dominated by the Th2 axis, involving mediators such as TSLP, IL-4, IL-13, IL-5, IL-33, IL-31, OX40, and the JAK/STAT signaling pathway. AD typically begins in infancy, with about 50% of patients developing symptoms before the age of one. The disease follows a chronic and relapsing course.

Epidemiological studies indicate that there are at least 230 million AD patients worldwide, with China having a substantial patient population exceeding 70 million, of which moderate-to-severe cases account for approximately 28%. In comparison, the U.S. has an estimated 16.5 million adult AD patients, with moderate-to-severe cases making up around 40%.

According to Precedence Research, the global AD drug market was value at 13.62 billion in 2023 and is projected to reach 13.62 *billion in* 2023 *and is projected to reach* 31.44 billion by 2034. Current treatment options vary in efficacy and include topical medications (e.g., corticosteroids [TCS], calcineurin inhibitors [TCI]), oral antihistamines, and biologics, each with its own advantages and limitations.

While conventional therapies like TCS, TCI, and oral antihistamines remain standard treatments, biologics such as dupilumab have significantly improved patients' quality of life. However, limitations such as slow onset, insufficient itch relief, and long-term safety concerns leave many patients' needs unmet. Another drug, the JAK inhibitor upadacitinib, faces safety-related challenges. In 2024, dupilumab's global sales surpassed $14 billion, highlighting the immense potential of the AD market and driving pharmaceutical companies to accelerate the development of differentiated therapies. Currently, competition in the AD field is primarily focused on target innovation: Among the top 10 AD clinical targets in China and globally, seven overlap, with IL-4Rα and JAK1 being the top two. In terms of clinical phases, only 14% of China's AD trials are in Phase 3 or later, compared to 23% globally (excluding Phase 2/3 trials), indicating that China's strategy remains largely fast-follow. Moreover, China's target landscape is more concentrated, with the top three targets (IL-4Rα, JAK1, and PDE4) accounting for 46% of clinical trials, whereas global AD clinical targets are more evenly distributed.

About SM17

SM17 is a novel, First-in-Class (FIC), humanized, IgG4-κ monoclonal antibody, which is a global first in-class monoclonal antibody drug targeting IL-25 receptor with the potential for treating AD, asthma, idiopathic pulmonary fibrosis and other immunological disorders. 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-9 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, especially in AD. Current approved therapies for AD, including biologics, can significantly improve eczema area and severity index (EASI) and patient’s quality of life, but they either are slow in response, especially in anti-pruritic effect, or have safety concerns. With the novel mechanism of action, SM17 hopefully will become a new and probably better treatment option for AD, which is fast in anti-pruritic response, effective in skin healing and safe, addressing the unmet medical needs not covered by current treatment modalities.

About Differences in Targeting the Receptor (IL-25R) vs the Ligand (IL-25)

Using AD as a model, stimulated skin will continuously release IL-25, and neutralizing IL-25 with antibodies does not instantly impart relief. SM17 uniquely blocks one of the IL-25 receptor subunits (IL-17RB) in a non-competitive manner. We have in-house data supporting that SM17 can block receptor signal transduction without affecting IL-25 engagement with the receptor, so SM17 can provide fast anti-pruritic and anti-inflammatory effects arising from IL-25/IL-25 receptor interactions.

Additionally, the number of receptors on cell surface is limited, and if sufficient antibodies against the receptor are added and all receptors blocked, therapeutic response will persist regardless of the amount of IL-25 released. This is the case for SM17, which blocks the limited number of receptors on cell surface. Once fully occupied, it stops the signaling regardless of IL-25 levels. This allows a fast, long-lasting inhibition and avoids high-dose requirements.

Contrarily, antibodies targeting IL-25 must neutralize the ligand directly, while AD skin continuously releases IL-25 such that anti-IL-25 therapies require high doses to “mop-up” all newly released IL-25. This delays itch and inflammation relief.

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About SinoMab BioScience Limited

SinoMab BioScience Limited is dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases. SinoMab is headquartered in Hong Kong with its R&D base in Hong Kong and production base in mainland China. The Company's flagship product Suciraslimab (SM03) is a potential global first-in-class mAb against CD22 for the treatment of rheumatoid arthritis (RA) and other immunological diseases. SM03 (Suciraslimab) has completed the Phase 3 clinical trial for RA in China and is pending NMPA's marketing approval for RA in China. In addition, the Company possesses other potential first-in-class drug candidates, some of which are already in clinical stage, with their indications covering rheumatoid arthritis (RA), Sjogren's syndrome (SS), systemic lupus erythematosus (SLE), atopic dermatitis (AD), idiopathic pulmonary fibrosis (IPF), asthma, and other diseases with major unmet clinical needs.

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