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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 IND APPROVAL FOR SM17 BY NMPA**

Reference is made to the 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 and 14 August 2023 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 that on 8 September 2023, the Investigational New Drug application (“**IND**”), for the treatment of patients with atopic dermatitis (“**AD**”) for the Company’s First-in-Class (FIC) therapeutic product SM17, was approved by the National Medical Products Administration of China (the “**NMPA**”). The IND approval would enable the Company to conduct comprehensive clinical development program in China which lead to the indication for treatment of AD. The Company plans to initiate a Phase I clinical study in China in the fourth quarter of this year to investigate the safety profile of SM17 in Chinese population and to initiate the clinical development program of SM17 for the treatment of allergic diseases.

SM17 is a novel, First-in-Class (FIC), humanized, IgG4-k 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.

A Phase I study for SM17 conducted in the US is near completion, with the Last Subject Last Visit (LPLV) scheduled later this month (September 2023). As of the date of this announcement, no drug-related serious adverse event has been reported, suggesting the product is well tolerated in human and shows a very good safety profile. 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 atopic dermatitis.

By Order of the Board  
**SinoMab BioScience Limited**  
**Dr. Shui On LEUNG**

*Executive Director, Chairman and Chief Executive Officer*

Hong Kong, 11 September 2023

*As at the date of this announcement, the executive director is Dr. Shui On LEUNG, the non-executive directors are Dr. Haigang CHEN, Mr. Xun DONG, Dr. Wenyi LIU, Mr. Lei SHI 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.*