

To: Business Editor

[For immediate release]



中國抗體製藥有限公司  
**SinoMab BioScience Limited**

## **IND Application for SinoMab's First-in-Class Asthma Therapeutic Product SM17 Approved by FDA**

[14 March 2022, Hong Kong] **SinoMab BioScience Limited** ("**SinoMab**" or the "**Company**", together with its subsidiaries, the "**Group**", stock code: **3681.HK**), a Hong Kong-based biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases, is pleased to announce that, the Investigational New Drug application ("IND"), for the treatment of patients with asthma for Company's First-in-Class (FIC) therapeutic product SM17 (Humanized anti-IL17RB monoclonal antibody for injection) was approved by the U.S. Food and Drug Administration ("FDA"). The IND approval would enable the Company to initiate the First-In-Human (FIH) study in the U.S. in the first quarter of 2022 at the earliest.

SM17 is the world's first monoclonal antibodies targeting IL17BR co-developed by SinoMab and LifeArc (a medical research charity based in the United Kingdom), and is known to be the world's first humanized which has a wide range of indications, including asthma, idiopathic pulmonary fibrosis etc. SM17 is a humanized, IgG4-κ monoclonal antibody targeting IL-17RB. The binding of SM17 to IL-17RB could suppress Th2 immune responses induced by interleukin-25, a critical cytokine classified as "alarmin", which has shown to be implicated in the pathogenesis of airway viral responses and allergic disease, such as asthma. Patients with severe, uncontrolled asthma are at a risk of recurrent asthma exacerbations and hospitalizations, and uncontrolled severe asthma is associated with increased mortality/morbidity, diminished quality of life and increased health expenditures. Current approved therapies for severe asthma, including biologics, can reduce asthma annual exacerbation rates to a certain extent. However, there is still an unmet medical need for additional effective therapies, particularly for patients who do not respond to current treatments. The Company expected that targeting upstream mediators of the Th2 inflammatory cascade, such as IL-17RB, will have a broad effect on airway inflammation. The Company believes the huge potential of SM17 to satisfy unmet medical needs in asthma treatment. SM17 has obtained positive data in preclinical research, and it is expected to provide a broader and more beneficial effect on asthma treatment if it is successfully commercialized.

**Dr. Shui On LEUNG, Chairman, Executive Director and Chief Executive Officer of SinoMab** said that: "The SM17 IND application was accepted by the FDA on February 11, 2022, and was approved only one month later, which fully reflects the FDA's recognition of the Company's candidate

products, and also confirms the efficient execution of the Company's new drug R&D program. The number of asthma patients and the market size of asthma products in the world have expanded continuously, the number of asthma patients in the PRC is increasing at a greater pace than the global rate and the asthma market in the PRC is expected to reach RMB65.0 billion by 2030 that there is still a huge need for innovative asthma treatment products with efficacy and safety by patients. We are therefore confident in the enormous prospects of SM17's clinical development. With several core products entering the clinical stage, the Company is constantly moving towards commercialization. In the future, we will accelerate our projects implementation, devote to the vision of independent innovation, further expand the product portfolio and potential indications to bring benefits to patients and create value for shareholders."

- END -

### **About SinoMab BioScience Limited**

SinoMab BioScience Limited (stock code: 3681.HK) is dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases. The Company's flagship product SM03 is a potential global first-in-target mAb against CD22 for the treatment of rheumatoid arthritis (RA) and is currently in Phase III clinical trial for rheumatoid arthritis in China, which has been recognized as one of the significant special projects of Significant New Drugs Development of the Twelfth Five-Year Plan Period and the Thirteenth Five-Year Plan Period. In addition, the Company possesses other potential first-in-target and first-in-class drug candidates, some of which are already in clinical stage, with their indications covering rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), pemphigus vulgaris (PV), non-Hodgkin's lymphoma (NHL), asthma, and other diseases with major unmet clinical needs.

This press release is issued by Porda Havas International Finance Communications Group for and on behalf of **SinoMab BioScience Limited**. For further information, please contact:

### **Porda Havas International Finance Communications Group**

Ms. Angela Shi	+852 3150 6778	<a href="mailto:angela.shi@pordahavas.com">angela.shi@pordahavas.com</a>
Ms. Tia Wong	+852 3150 6739	<a href="mailto:tia.wong@pordahavas.com">tia.wong@pordahavas.com</a>