



中國抗體製藥有限公司

**SinoMab BioScience Limited**

**Great Potential in RA Therapeutic Market  
Sinomab Announces Latest Progress of its Drug Candidate SM03  
Phase III Clinical Trial for the Treatment RA**

[20 November 2019, Hong Kong] **SinoMab BioScience Limited** (“**SinoMab BioScience**” 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 its latest progress of SM03 phase III clinical trial for the treatment rheumatoid arthritis.

SM03 is a chimeric mAb specific to the B cell restricted antigen CD22 developed for the treatment of rheumatoid arthritis (“RA”), and other immunological diseases such as systemic lupus erythematosus (“SLE”) and Sjogren’s syndrome (“SS”). Currently, drugs for the treatment of RA marketed and in the pipeline in the PRC market are mostly TNF- $\alpha$  based. As a potential global first-in-target mAb for the treatment of RA, SM03 is a recombinant immunoglobulin IgG1 monoclonal antibody. Its efficacies for RA and superior safety profile have been substantiated in the Phase II clinical trial led by Peking Union Medical College.

As the drug candidate coming the closest to commercialization, SM03 is currently in Phase III clinical trial for RA in China. The trial is led by the Chinese Academy of Medical Sciences & Peking Union Medical College and involves 44 medical institutions including Nanjing Drum Tower Hospital, the Affiliated Hospital of Nanjing University Medical School, the Second Affiliated Hospital of Harbin Medical University and the Affiliated Hospital of Shanxi Medical University. The latest statistics show that approximately 300 patients have taken the treatment. The Company plans to file NDA for SM03 with National Medical Products Administration of the PRC in the second half of 2020, as well as conduct a bridging clinical study in Australia in the first quarter of 2020 and initiate global R&D in the United States and Europe as planned. SM03 is expected to be marketed in 2021 the soonest.

The total sales revenue of RA therapeutics market in the PRC grew from RMB7.7 billion in 2014 to RMB11.5 billion in 2018. With the significant improvements in RA diagnosis and increase in patients’

income level, the RA therapeutics market in the PRC is expected to reach RMB28.0 billion by 2023 and RMB83.3 billion by 2030. Since the twelfth Five-year Plan, the country has been strongly supporting the development of innovative drugs for the prevention and treatment of serious diseases, including immunological diseases. The National Health Commission of the PRC recently announced the “Construction and Management Guideline on Rheumatology Department in General Hospitals (Trial)” (the “Guideline”). It requires qualified hospitals to improve the construction and development of rheumatology department in general hospitals and diagnosis of rheumatic diseases. Those unqualified hospitals are required to strengthen construction to establish a normalized rheumatology department. Professor Zeng Xiaofeng, chairman of Chinese Rheumatology Association and director of rheumatology, Peking Union Medical College Hospital, commented in an interview, that rheumatology is an emerging discipline in China. The introduction of the Guideline shows that the nation attaches great importance to rheumatology and benefits the development of the discipline.

**Dr. Shui On LEUNG, the Executive Director, Chairman of the Board and Chief Executive Officer of SinoMab BioScience Limited**, said, “SinoMab is dedicated to the immunological diseases field and devote to the development of novel drugs to fulfill unmet medical needs. The RA therapeutic market in the PRC has great potential. Supported by national policies, the development of rheumatology discipline has come to a golden era. Looking ahead, we will rapidly advance SM03 towards commercialization. We’re confident that its unique MOA and first-in-target nature will enable SM03 to establish itself as an effective treatment option for RA, thus to bring cashflow to the Company to support the further development of our drug candidate pipeline, improve our competitiveness and create returns to shareholders and investors.”

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### **About SinoMab BioScience Limited**

**SinoMab BioScience Limited** (“SinoMab” or the “Company”, 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 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, systemic lupus erythematosus, non-Hodgkin's lymphoma, 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:

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