



中國抗體製藥有限公司
SinoMab BioScience Limited

SinoMab Announces Clinical Results on its First-in-target SM03 at EULAR 2020 Congress Pipeline of Drug Candidates Has Vast Potential in the Future

[10 June 2020, Hong Kong] **SinoMab BioScience Limited** (“**SinoMab**” or the “**Company**”, 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, made an oral presentation titled “Efficacy and safety of SM03, a Recombinant Anti-human CD22 Monoclonal Antibody in Chinese Patients with Rheumatoid Arthritis: A Phase II randomized, double-blind, multi-dose, placebo-controlled study” in the evening on 5th June, 2020 at the European League Against Rheumatology (“**EULAR**”) 2020 Congress(the “**Congress**”). Professor Zhang Fengchun, the head of Internal Medicine Department of Peking Union Medical College Hospital (PUMCH) and the leading principal investigator of the Phase II clinical study of SM03, reported the results of the study as the keynote speaker.

Professor Zhang said that SM03 has shown significant efficacy for the treatment for RA without increase in adverse events. Been invited to announce the clinical results at the Congress showed the great emphasis and expectation worldwide for SM03. Professor Zhang also expressed his confidence in SM03’s next stage study and marketing in the future. Moreover, Professor Zhang said B cells play an important role in immunological diseases. The positive results of SM03 for the treatment for RA will benefit the exploration of potential indications against other B cells-related diseases.

As a potential global first-in-target anti-CD22 mAb for the treatment of RA, SM03 has been recognized by the PRC’s Ministry of Science and Technology as one of the significant special projects of Significant New Drugs Development of the Twelfth and Thirteenth Five-Year Plan Period for two consecutive times. SM03 has completed its Phase II clinical study for the treatment of RA led by the Peking Union Medical College Hospital, aiming to evaluate its efficacy and safety for patients with moderate to severe active RA. Phase II clinical study took a period of 24 weeks and enrolled 156 patients with a history of MTX treatment failure, who were randomly divided into three groups, namely Placebo, Low dose and High dose. The study design followed international standards for clinical trials of new drugs and conducted regular evaluation on efficacy and safety according to the requirements of international new drug applications. Statistics related to the oral presentation are

as follow: the enrolled Chinese patients with active RA, SM03 in combination with methotrexate, demonstrated a good safety and tolerance, throughout 24 weeks of treatment, especially in terms of infusion-related reactions and treatment-related infections. No patient reported severe treatment-emergent infections or any secondary malignancies, during the study. Moreover, SM03 has demonstrated a good safety profile, especially in terms of treatment-related infection, secondary malignancy and low immunogenicity. (EULAR abstract number: OP0210)

Dr. Shui On Leung, the Executive Director, Chairman and Chief Executive Officer of SinoMab, said in the video interview, that SM03 is currently in Phase III clinical trials. Although the timeframe is extended due to the uncertainties brought by COVID-19, the enrolment is expected to be completed by the end of this year and the Biologics Licence Application is estimated to be filed by the end of 2021. Another drug developed by SinoMab, SN1011, which is one of the only two BTK inhibitor in clinical trials worldwide, is in Phase I clinical trial in Australia. The single arising dose study has completed and shown satisfying safety evaluation. The submission of Investigational New Drug (“IND”) in China is in preparation as well. Furthermore, SM17, SinoMab’s first-in-class mAb against the receptor IL17BR, is developed for the treatment of potential indications including allergic asthma and idiopathic pulmonary fibrosis (IPF) and is expected to file IND in America or the European region. Dr. Leung said that SinoMab strives to become a global leader in the innovation of therapeutics for autoimmune diseases. Focusing on the development of novel drugs, in addition to the treatment of immunological diseases, SinoMab is also exploring therapeutics for cancers and other rare diseases in both domestic and overseas markets. To strengthen innovative R&D capability, the Company plans to introduce a target screening platform. And two to three drugs are estimated to initiate clinical trials in the next two years. At this stage, numerous international pharmaceutical giants have expressed cooperative intentions.

Professor Zhang added, SinoMab has found numerous targets for the treatment of immunological diseases and obtained the potential to develop more innovative therapeutics to contribute to the therapeutics for the treatment of immunological diseases.

About European League Against Rheumatology 2020 Congress

European League Against Rheumatology 2020 Congress is hosted by European League Against Rheumatology (EULAR) and enjoys an important role in global rheumatology research. The EULAR Congress initiated in 2000. Physicians, scientist and arthritis/rheumatism patients, health professionals and representatives from pharmaceutical industry from all over the world are gathered to share the cutting-edge research results in rheumatology field. Nowadays, the EULAR Congress has become an important platform for scientific and clinical information in Europe and a well-known forum for the communication between global rheumatologists. The scientific program of EULAR Congress covers topics including clinical innovation, clinical, transformation and fundamental science, dedicating to improving health condition of people suffering from rheumatic musculoskeletal disease.

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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