

To: Business Editor

[For immediate release]



中國抗體製藥有限公司
SinoMab BioScience Limited

SinoMab Announces IND APPLICATION FOR SN1011 APPROVED BY NMPA

[20 April 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, on 19 April 2022 (after trading hours), an Investigational New Drug application ("IND", for multiple sclerosis) for SN1011 was approved by the National Medical Products Administration of China (the "NMPA"). The IND approval would enable the Company to initiate the Phase II clinical study to evaluate the efficacy and safety of SN1011 in patients with multiple sclerosis in China. The planned first patient enrollment is in the fourth quarter of 2022.

SN1011 is the Company's third generation, covalent reversible BTK inhibitor designed for higher selectivity, superior efficacy and improved safety for the long-term treatment of systemic lupus erythematosus, pemphigus vulgaris, multiple sclerosis, rheumatoid arthritis, and other immunological diseases. SN1011 differentiates from existing BTK inhibitors currently available in the market, such as Ibrutinib, in terms of mechanism of action, affinity, selectivity and safety.

The Phase I study (first-in-human clinical trial) of SN1011 was conducted in Australia and China in 2019 and completed in July 2021, which has demonstrated good safety and pharmacokinetics profile. Currently, the IND application for SN1011 in the treatment of systemic lupus erythematosus (SLE), pemphigus vulgaris (PV) and multiple sclerosis (MS) have been approved by NMPA, the Company plans to launch the Phase II clinical study for pemphigus in the third quarter of 2022. In addition to the approval of this IND, the Company is planning an IND submission for multiple sclerosis (MS) in the U.S. in the second quarter of 2022, thereby accelerating the initiation of a global phase II trial in the third quarter of 2022.

MS is a demyelinating disease, which potentially damages the patient's brain and spinal cord. MS may cause a wide range of symptoms, including but not limited to vision problems and movement disorders. Global MS prevalence reached 2.7 million people in 2018 and is expected to increase to 3.1 million people in 2023 at a CAGR of 2.8% from 2018, and 3.7 million people in 2030 at a CAGR of 2.7% from 2023. Global MS market expanded to US\$23.0 billion in 2018, and is expected to reach US\$30.8 billion in 2023 at a CAGR of 6.0% from 2018, and US\$48.9 billion in 2030 at a CAGR of 6.8% from 2023.

Dr. Shui On LEUNG, Chairman, Executive Director and Chief Executive Officer of SinoMab said that: "The IND application for MS for SN1011 was accepted by the NMPA at the beginning of

the year, and was approved only three months later, which fully reflects the NMPA's recognition of the Company's candidate products, and also confirms the efficient execution of the Company's new drug R&D program. The approval of this IND application is the third indication of SN1011 in China following the approval of IND application for SLE and pemphigus, fully demonstrating the great potential of our innovative BTK inhibitor in the field of the treatment of autoimmune diseases. We are absolutely confident in the enormous prospects of SN1011's clinical development, we will also accelerate clinical trials and continuously expand the scope of potential indications. In the future, we will accelerate our R&D projects implementation, devote to the vision of independent innovation, further expand the product portfolio and potential indications, dedicate to exploring safe and effective treatments for patients suffering from autoimmune diseases worldwide."

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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:

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