porda havas/amo
strategic advisors

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 ACCEPTED BY NMPA CDE

Continuously expanding the scope of potential indications for SN1011

[9 June 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 6 June 2022, an Investigational New Drug application ("**IND**", for neuromyelitis optica spectrum disorder ("**NMOSD**")) for SN1011 has been filed with and accepted by the Center for Drug Evaluation (the "**CDE**") of the National Medical Products Administration of China (the "**NMPA**"). The Company plans to initiate the Phase II clinical study in China upon approval of the present IND. The present IND submission, once granted, will enable the Company to conduct clinical program in China for treatment of NMOSD.

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

The Phase I clinical study (first-in-human clinical trial) of SN1011 was conducted in Australia and China in 2019 and completed in July 2021, which has demonstrated improved safety and good 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 of SN1011 for pemphigus in the third quarter of 2022. The Company is also 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.

NMOSD is an autoimmune-mediated inflammatory demyelinating disease of the central nervous system with predominant involvement of the optic nerve and spinal cord. The pathogenesis of NMOSD is mainly associated with aquaporin-4 (AQP4) antibodies and is a separate disease entity from multiple sclerosis, with severe optic neuritis and longitudinal extensive transverse myelitis as the main clinical features. However, the cause of NMOSD is unknown, with a combination of environmental factors such as smoking, low vitamin D levels, EBV infection and genetic susceptibility contributing to the development of the disease.

In 2020, according to inpatient registration data published in China, the incidence of NMOSD is about 0.278 (100,000 people/year), with children at 0.075 (100,000 people/year) and adults at 0.347 (100,000 people/year). NMOSD is seen at all ages, with young adults being the most common, with the average age of onset being 40 years. NMOSD is a highly recurrent and disabling disease, with 40-60% of patients experiencing a recurrence within one year and 90% within three years, and 50% of patients with a natural course of the disease having severe visual or motor impairment within 5-10 years. Currently, there are only three drugs officially approved by the US FDA or the European

Union for the treatment of NMOSD, including complement inhibitors, IL-6 receptor blockers and B-lymphocyte-depleting agents. On 30 April 2021, the NMPA officially approved satralizumab for treatment of AQP4-IgG positive patients over the age of 12 years, making it the first drug approved for NMOSD treatment indications in mainland China. An IND application for NMOSD for SN1011 of SinoMab has been accepted by the CDE of the NMPA, and once approved, will facilitate the clinical research and development of new drugs for NMOSD in China.

Dr. Shui On LEUNG, Chairman, Executive Director and Chief Executive Officer of SinoMab said that: "NOMSD is the fourth indication of SN1011 in China following the approvals of IND application for systemic lupus erythematosus (SLE), pemphigus vulgaris (PV) and multiple sclerosis (MS), and is also the third IND application submitted by the Company to the regulatory authority this year, which fully reflects the team's ability to simultaneously advance the research and development of multiple drug candidates and to effectively execute and communicate. The potential indications for SN1011 continue to expand, BTK inhibitor has a wide range of applications in the field of treatment of autoimmune diseases and huge future market potential. We believe that if the SN1011 product is successfully approved and commercialized in the future, it is expected to bring positive benefits to the Company, provide new options for the treatment of various autoimmune diseases and bring hope to the majority of patients."

- 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	angela.shi@pordahavas.com
Ms. Tia Wong	+852 3150 6739	tia.wong@pordahavas.com