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## SINO BIOPHARMACEUTICAL LIMITED 中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability) Website: www.sinobiopharm.com (Stock code: 1177)

## VOLUNTARY ANNOUNCEMENT APPROVAL FOR MARKETING OF PENPULIMAB INJECTION BY THE US FDA

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the penpulimab injection co-developed by the Group has been approved by the United States Food and Drug Administration (US FDA) for marketing. The drug is indicated 1) in combination with either cisplatin or carboplatin and gemcitabine, for the first-line treatment of adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC); and 2) as a single agent, for the treatment of adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Penpulimab is currently the only novel differentiated PD-1 monoclonal antibody utilizing the IgG1 subtype with Fc engineering, demonstrating enhanced efficacy in immunotherapy while minimizing adverse reactions. Four indications for penpulimab have been approved by the National Medical Products Administration (NMPA) in China, including: in combination with chemotherapy for the first-line treatment of metastatic NPC, in combination with chemotherapy for the first-line treatment of netastatic squamous non-small cell lung cancer, as a single agent for the treatment of relapsed or refractory classical Hodgkin's lymphoma after at least two lines of systemic chemotherapy, and as a single agent for the treatment of second-line and above metastatic NPC. In addition, in November 2024, the new drug application for penpulimab in combination with anlotinib for the first-line treatment of advanced hepatocellular carcinoma was accepted by the NMPA.

The Group will actively promote the development of indications for penpulimab and expedite the development of international markets to meet the urgent clinical needs of patients around the world.

By order of the Board Sino Biopharmaceutical Limited Tse, Theresa Y Y *Chairwoman* 

Hong Kong, 25 April 2025

As of the date of this announcement, the Board of the Company comprises six executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, and Mr. Tian Zhoushan, and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.