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
ACCEPTANCE OF NEW DRUG APPLICATION FOR KRAS G12C INHIBITOR "GARSORASIB TABLET (D-1553)"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the National Medical Products Administration of the PRC has formally accepted the new drug application ("**NDA**") for KRAS G12C Inhibitor "Garsorasib Tablet (D-1553)", which is codeveloped by the Group for the treatment of locally advanced or metastatic non-small cell lung cancer ("**NSCLC**") with disease progression following or intolerant to prior first-line systemic therapy and with confirmed KRAS G12C mutation. At present, there is no KRAS G12C targeted drug available in the PRC market.

D-1553 is the first domestic independently developed KRAS G12C inhibitor to enter clinical trials stage and has been subject to international multicenter clinical trials in the United States, Australia, PRC, Korea and other countries and regions. In June 2022, D-1553 was granted Breakthrough Therapy designation by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration, being the first domestic KRAS G12C inhibitor which was granted Breakthrough Therapy designation by CDE. The acceptance of the NDA is based on the results of a clinical Phase II, single-arm registration (CTR20220745) study conducted in China. The study aims to evaluate the safety, tolerability and efficacy of D-1553 single agent in advanced NSCLC subjects who have failed or are intolerant to standard therapy and with a KRAS G12C mutation, and the results of the study will subsequently be published in academic journals/conferences.

As compared with other drugs with the same target approved and marketed in the world, D-1553 tops the list of efficacy and safety. Results of early phase clinical trials showed that D-1553 had good safety and antitumour activity in NSCLC patients with KRAS G12C mutation, with an objective response rate ("**ORR**") of 40.5%, a disease control rate ("**DCR**") of 91.9%, a median progression-free survival rate ("**mPFS**") of 8.2 months, the mPHS of which was higher than other drugs with the same target approved by US Food and Drug Administration ("**FDA**"). Such early trial results were selected for oral presentation at the 2022 World Conference on Lung Cancer ("**WCLC**") and published in April 2023 in the Journal of Thoracic Oncology ("**JTO**").

KRAS mutations commonly exist in various high lethality cancers, of which KRAS G12C is one of the most common KRAS mutations, representing approximately 44% of all KRAS mutations. KRAS G12C mutation is more common in lung, colorectal, pancreatic and bile duct cancers. From 2016 to 2020, the number of new patients in the PRC suffering from major KRAS G12C mutation cancers increased from 38,000 to 43,000, and it is estimated that such number will reach 58,000 in 2023. At present, patients with KRAS G12C mutations have a poorer prognosis and are susceptible to resistance to standard therapies, and treatment options are very limited in the event of failure of chemotherapy or immunotherapy, accordingly there is a great unmet clinical need.

D-1553 has high potential for various indications. Save for the indication in this NDA acceptance, the Group is currently cooperating with InventisBio Co. Ltd. ("**InventisBio**") to promote clinical trials of first-line treatment for NSCLC and other solid tumours, and it is anticipated that the indications for D-1553 will be further expanded in the coming years and hopefully another heavyweight oncology product that is comparable to Anlotinib will be created.

Regarding Project D-1553

In August 2023, Chia-Tai Tianqing Pharmaceutical Group Co., Ltd. ("**Chia-Tai Tianqing**"), a subsidiary of the Company, entered into an exclusive license and cooperation agreement with InventisBio. Chia-Tai Tianqing was granted an exclusive license by InventisBio to develop, register, manufacture and commercialise D-1553 in Mainland China. Meanwhile, based on potential future data sharing cooperation, Chia-Tai Tianqing will be granted a certain proportion of rights outside of Mainland China in due course. The acceptance of the NDA makes D-1553 probable to become a leading domestic KRAS G12C inhibitor marketed in China, benefiting domestic tumour patients at the soonest, letting more patients have access to the drug and treating more diseases.

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

Hong Kong, 2 January 2024

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin 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.