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
KRAS G12C INHIBITOR "GARSORASIB TABLET (D-1553)" INCLUDED IN THE BREAKTHROUGH THERAPEUTIC DESIGNATION PROCESS

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announced that KRAS G12C Inhibitor "Garsorasib Tablet (D-1553)", which is jointly developed by the Group, has been included in the Breakthrough Therapeutic Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. There are a total of two indications for inclusion: 1) for the treatment of locally advanced or metastatic pancreatic ductal adenocarcinoma with KRAS G12C mutation in patients who have failed first-line therapy; and 2) in combination with cetuximab injection for the treatment of KRAS G12C mutation-positive and surgically unresectable locally advanced or metastatic colorectal cancers in patients who have failed second-line standard therapy (including oxaliplatin, irinotecan, 5-fluorouracil and anti-VEGF monoclonal antibody).

Previous studies have shown that D-1553 tablets have excellent efficacy and a favourable safety profile in these indications. Accordingly, the Group has obtained consent from the CDE to commence the Phase II single-arm registrational clinical study of D-1553 tablets for the second-line and above treatment of advanced pancreatic ductal adenocarcinoma with KRAS G12C mutation in patients who have failed standard treatment, and the Phase II clinical study will be initiated in China soon. The Group is also in active communication with the regulatory authorities regarding the registration study in the direction of colorectal cancer.

D-1553 tablet is a KRAS G12C inhibitor with high activity and high selectivity, which can block the abnormal KRAS signals in cancer cells through specifically and irreversibly binding with KRAS G12C mutant proteins to achieve anti-tumour effect. In December 2023, the new drug marketing application of D-1553 was formally accepted by the CDE 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.

KRAS (Kirsten rat sarcoma viral oncogene homologue) is one of the oncogenes with the highest mutation rate in human malignancies and is an important driver gene for cancer in tumours with high mortality rates such as lung cancer, colorectal cancer and pancreatic cancer. The KRAS G12C subtype mutation is one of the most common KRAS mutations, occurring in about 3% of patients with colorectal cancer, and about 1%-2% of patients with pancreatic cancer and other patients with various solid tumours. Tumours carrying the KRAS G12C mutation have a poor prognosis with the usual characteristics of easy metastasis, late diagnosis and short survival. Currently, there is a lack of standard treatment specifically aiming at the target and poor response to the existing commonly used treatment, resulting in an unmet clinical need with urgency for these patients.

D-1553 tablet is another innovative drug of the Group recently included in the BTD process. The recognition of BTD will facilitate the early launch of the new drug for the benefit of the patients.

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

Hong Kong, 11 June 2024

As at 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.