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
KRAS G12C INHIBITOR "GARSORASIB" TABLET

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the KRAS G12C inhibitor "Garsorasib" tablet (trade name: Anfangning (安方寧)), co-developed by the Group, has obtained approval for marketing from the National Medical Products Administration of China for the treatment of adult patients with KRAS G12C-mutated advanced non-small cell lung cancer (NSCLC) who have received at least one systemic therapy.

Lung cancer is a malignant tumour with the highest incidence and mortality rate globally. In 2022, the number of new cases of lung cancer in China exceeded 1.06 million[1, 2]. NSCLC accounts for approximately 85% of all lung cancer cases[3]. Among the Chinese population, approximately 3% of NSCLC patients harbored KRAS G12C mutation[4]. Some of these patients have relatively poor prognoses, with relatively few drugs targeting this mutation available globally. With limited treatment options, patients in China still mainly rely on chemotherapy, and there are high unmet clinical needs.

The approval was mainly based on a multicenter, single-arm and open-label pivotal phase II study (NCT05383898) conducted in patients with KRAS G12C mutation-positive locally advanced or metastatic NSCLC, which was intended to evaluate the efficacy, safety and tolerability of garsorasib as a monotherapy for KRAS G12C-mutant NSCLC. The latest results of the study were announced as an oral presentation at the 2024 World Conference on Lung Cancer (WCLC).

As of 17 May 2024, a total of 123 patients were enrolled and treated with garsorasib 600mg twice daily (BID), with a median follow-up of 12.3 months, an objective response rate (ORR) of 52.0%, a disease control rate (DCR) of 88.6%, a median progression-free survival (PFS) of 9.1 months and a median overall survival (OS) of 14.1 months, thus making it the targeted drug with the longest OS among currently marketed KRAS G12C inhibitors in the world[5].

The approval of garsorasib will further enhance the level of precision-targeted treatment for tumors in China and provide patients with new treatment options. Given the huge potential of garsorasib for indications, the Group will further explore the multi-indication potential of the drug to allow more patients to enjoy the health and well-being brought about by technological advancement.

About Garsorasib

Garsorasib is a new and highly effective KRAS G12C inhibitor that can inhibit the carcinogenic signaling of KRAS G12C and inhibit tumor cell proliferation, thereby achieving anti-tumor effects. 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 Co. Ltd. ("**InventisBio**"). Chia Tai Tianqing was granted an exclusive license by InventisBio to develop, register, manufacture and commercialise garsorasib in Mainland China. Meanwhile, based on potential future cooperation in data sharing, Chia Tai Tianqing will be granted a certain proportion of revenue outside of Mainland China in due course.

In addition to the approved indication, the Group has been working with InventisBio to promote the clinical trials of garsorasib for the first-line treatment of NSCLC and the first-line treatment of other solid tumors including pancreatic cancer and colorectal cancer. In June 2024, two new indications of garsorasib were included in the Breakthrough Therapeutic Designation process by the Center for Drug Evaluation of the National Medical Products Administration of China, namely 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). The Group will expedite the clinical development of garsorasib, and expect to further expand the indications of garsorasib in the next few years. Garsorasib is expected to develop as the next blockbuster product for tumors comparable to anlotinib.

Sources:

[1] Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries[J]. CA: a cancer journal for clinicians, 2024, 74(3): 229-263.

[2] Han B, Zheng R, Zeng H, et al. Cancer incidence and mortality in China, 2022[J]. Journal of the National Cancer Center, 2024, 4(1): 47-53.

[3] Jie Guangling, Yang Ying, Yu Yongfeng, et al. Annual progress in the treatment of non-small cell lung cancer (非小細胞肺癌治療年度進展) 2023[J]. Chinese Medical Journal (中華醫學雜誌), 2024, 104(36): 3446-3454.

[4] Liu SY, et al. Clinical characteristics and prognostic value of the KRAS G12C mutation in Chinese non-small cell lung cancer patients. Biomark Res. 2020 Jun 25;8:22.

[5] Z. Li, et al. Garsorasib in KRAS G12C-mutated Non-small-cell Lung Cancer: Updated Results from a Phase 2 Study. 2024-LBA-1246-WCLC.

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

Hong Kong, 11 November 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.