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
PUBLICATION OF STUDY FINDINGS OF PHASE II CLINICAL TRIAL OF KRAS G12C INHIBITOR "GARSORASIB TABLET (D-1553)" IN THE LANCET RESPIRATORY MEDICINE

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the study findings of the Phase II clinical trial of the KRAS G12C inhibitor "garsorasib tablet (D-1553)" co-developed by the Group have been published in the internationally renowned journal *The Lancet Respiratory Medicine* (IF: 76.2). This marked the first time for a domestic KRAS G12C inhibitor to be published in a journal of The Lancet Group.

Study Method

The current study, published in *The Lancet Respiratory Medicine*, is an open-label, multicenter, single-arm registration phase II study (NCT05383898) in China designed to evaluate the efficacy and safety of garsorasib in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with KRAS G12C mutation.

The primary enrolment criteria were: patients with locally advanced or metastatic NSCLC with KRAS G12C mutations, prior progressive disease or toxic intolerant to anti-PD-(L)1 therapy and platinum-based chemotherapy, and measurable lesions according to RECIST v1.1 criteria. The primary endpoint was objective response rate (ORR) assessed by the Blinded Independent Review Committee (IRC) according to RECIST v1.1. The secondary endpoints included duration of response (DOR), disease control rate (DCR), time to response (TTR), progression-free-survival (PFS), overall survival (OS), safety, and population pharmacokinetics.

Study Findings

As of 17 November 2023, a total of 123 patients were enrolled and treated with garsorasib 600mg twice daily (BID), in which 108 patients (88%) were male, with a median age of 64 (interquartile range: 59-68) and ECOG PS scores of 0 and 1 in 11% and 89% patients, respectively. As of the data cut-off date, 82 patients (67%) had discontinued treatment. The median follow-up was 7.9 months (interquartile range: 6.3-10.4).

In terms of efficacy, 1 patient had a complete response, 60 patients had a partial response, and 48 patients were stable. The IRC-confirmed ORR was 50% (61/123, 95% CI, 41-59) and the DCR was 89% (109/123, 95% CI, 82-94). The median DOR was 12.8 months (95% CI, 6.2-NE). The median PFS was 7.6 months (95% CI, 5.6-9.7), and the median OS has not yet been reached.

In terms of safety, a total of 117 patients (95%) reported treatment-related adverse events (TRAEs), with 61 patients (50%) experiencing adverse events of grade 3 or higher. The most reported (≥20%) TRAEs (any grade) were elevated aspartate aminotransferase, elevated alanine aminotransferase, and elevated γ-glutamyl transferase, anemia, elevated blood bilirubin, elevated serum alkaline phosphatase, vomiting, and nausea. 37 patients (30%) and 51 patients (41%) had dose reductions and dose interruptions due to TRAEs, respectively. No patients discontinued treatment due to TRAEs. No new safety signals were identified, and most of the adverse events were well controlled.

Conclusions of the Study

The results of the study showed that garsorasib showed a higher tumor response rate and a longer duration of response (ORR: 50%, DCR: 89%, median DOR: 12.8 months, median PFS: 7.6 months) in NSCLC patients harboring the KRAS G12C mutation, and it was also well tolerated and controllable.

About Garsorasib

Garsorasib is the first domestic independently developed KRAS G12C inhibitor to enter clinical trial stage and is also the first domestic KRAS G12C inhibitor which was granted Breakthrough Therapy designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. In December 2023, the new drug application for garsorasib for the treatment of locally advanced or metastatic NSCLC with disease progression following or intolerant to prior first-line systemic therapy and with confirmed KRAS G12C mutation has been accepted and has been included in the priority review and approval procedures in January 2024.

Currently, international multi-center clinical studies of D-1553 as a monotherapy and as drug combination in the first-line treatment of NSCLC and other solid tumors such as colorectal cancer are ongoing, and some of the study results have been published on influential international academic conference platforms, all of which have demonstrated its good safety and anti-tumor activity.

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 data sharing cooperation, Chia Tai Tianqing will be granted a certain proportion of revenue outside of Mainland China in due course.

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.