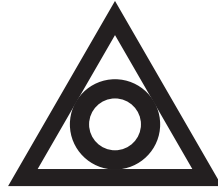


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SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

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(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
APPROVAL FOR MARKETING OF CATEGORY 1 INNOVATIVE DRUG
ENVONALKIB CITRATE CAPSULES “ENVONALKIB (TQ-B3139)”

The board of directors (the “Board”) of Sino Biopharmaceutical Limited (the “Company”, together with its subsidiaries, the “Group”) announces that the category 1 innovative drug Envonalkib Citrate Capsules “Envonalkib (TQ-B3139)” (trade name: Anluoqing (安洛晴)) self-developed by the Group has obtained approval for marketing from the National Medical Products Administration of China for the treatment of anaplastic lymphoma kinase (ALK)-positive patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not been treated with ALK inhibitors.

The approval of Envonalkib, a novel ALK inhibitor independently developed by the Group, for the indication of first-line treatment of ALK-positive NSCLC is based on the results of a multi-center, randomised, controlled phase III clinical study of Envonalkib versus Crizotinib for the first-line treatment of ALK-positive advanced NSCLC (NCT04009317). The results of the study were published on 14 August 2023 in *Signal Transduction and Targeted Therapy* (IF: 39.3).

Clinical Data: Efficacy Significantly Better than Crizotinib, Significant Benefit in Patients with Brain Metastases^[1]

As of 31 August 2022, the median progression-free survival (mPFS) results assessed by the Independent Review Committee (IRC), the primary endpoint of such phase III study, showed that the mPFS of Envonalkib and Crizotinib was 24.87 months vs. 11.60 months, respectively, with HR=0.47 (P<0.0001) and a 53% reduction in the risk of tumour recurrence. The difference between the two groups was statistically significant. Meanwhile, in the analysis of all key subgroups, Envonalkib demonstrated a significant advantage, especially for patients with baseline brain metastases (HR=0.36). The overall remission rate (ORR) for patients with assessable baseline brain metastases lesions in both groups was 78.95% vs. 23.81%, and the duration of remission (DoR) was 25.82 months vs. 7.39 months (HR=0.12);

and the time to progression (TTP) for patients with baseline brain metastases lesions in both groups was 30.32 months vs. 8.28 months (HR=0.31). The results demonstrated that Envonalkib may significantly delay disease progression or reduce the risk of progression of new brain metastases in patients with brain metastases. The safety results of this study showed that the adverse events associated with the study drug were generally similar to those of previous analogues, and the overall safety profile was manageable with no new safety signals.

Market Layout: High Incidence of Lung Cancer and High Unmet Need for Brain Metastases in China

Lung cancer is a malignant tumour with a high incidence and mortality rate in China and globally. According to a study of “Cancer incidence and mortality in China, 2016” released by the National Cancer Center in 2022, the number of new cases of lung cancer in China reached 828,000 per year, and the number of deaths was 657,000 per year, with the incidence rate and mortality rate both ranked the first among all types of cancer^[2]. Among NSCLC patients, the incidence of ALK mutation is 3%~7%. With the aging of China’s population and the popularity of molecular diagnostic and therapeutic techniques, the diagnosis rate of new ALK-positive NSCLC patients has shown an increasing trend year by year^[3]. Crizotinib is a first-generation ALK inhibitor, and its efficacy is significantly better than that of chemotherapy, but disease progression still occurs in nearly half of the patients who have been on the drug for about 1 year, and Crizotinib has a weaker penetrating ability to the central nervous system, which cannot effectively control the occurrence and development of brain metastases, with limited benefits to patients, leaving an unmet clinical need.

Envonalkib Citrate Capsules is another category 1 innovative drug of the Group approved following Anlotinib Hydrochloride Capsules, Unecritinib Fumarate Capsules and Benmelstobart Injection. This means that the layout of the Group’s innovative products in the field of lung cancer has continued to be enriched, which is of great significance to the Group’s innovative development.

Sources:

- [1]. Yang Y, Min J, Yang N, et al. Envonalkib versus crizotinib for treatment-naïve ALK-positive non-small cell lung cancer: a randomized, multicenter, open-label, phase III trial. *Signal Transduct Target Ther.* 2023;8(1):301.
- [2]. Rong S, Si W, Hong M, et al. Cancer incidence and mortality in China, 2016. *Journal of the National Cancer Center.* 2 (2022) 1–9.
- [3]. Liu X. Horizon – interpretation of ALK-positive non-small cell lung cancer Chinese story. *Zhongguo Fei Ai Za Zhi.* 2015 Feb;18(2):59-60.

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

Hong Kong, 19 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.