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 CATEGORY 1 INNOVATIVE DRUG BENMELSTOBART INJECTION "BENMELSTOBART (TQB2450)" IN COMBINATION WITH ANLOTINIB HYDROCHLORIDE CAPSULES FOR THE INDICATION OF FIRST-LINE TREATMENT FOR SMALL CELL LUNG CANCER

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 Benmelstobart Injection "Benmelstobart (TQB2450)" (Trade name: 安得衛) self-developed by the Group has obtained approval for marketing from the National Medical Products Administration of China for use in first-line treatment for patients with extensive-stage small cell lung cancer (ES-SCLC), in combination with Anlotinib Hydrochloride Capsules, carboplatin and etoposide.

Benmelstobart is a humanized PD-L1 monoclonal antibody self-developed by the Group that blocks the binding of PD-L1 to PD-1 and B7.1 receptors on the surface of T cells, restoring T cell activity and thereby enhancing the immune response. Early clinical data have demonstrated that Benmelstobart in combination with Anlotinib have synergistic effects on a number of tumour types (e.g. non-small cell lung cancer, soft tissue sarcoma, renal cell carcinoma, endometrial cancer, ovarian cancer, hepatocellular carcinoma, cholangiocarcinoma, etc.)[1-4].

The approval for the indication of first-line treatment for small cell lung cancer is based on a randomised, double blinded, placebo control, multicenter Phase III clinical trial of Benmelstobart in combination with Anlotinib, carboplatin and etoposide for the first-line treatment of small cell lung cancer (ETER701).

ETER701 study results were presented at the 2023 World Conference on Lung Cancer (WCLC): As of 14 May 2022, the median progression-free survival (mPFS) was 6.9 months (95% CI: 6.18-8.25) and 4.2 months (95% CI: 4.17-4.24) in the Benmelstobart in combination with Anlotinib and chemotherapy group and chemotherapy-only group, respectively, and the risk of tumour recurrence was reduced by 68%, with a statistically significant difference. The median overall survival (mOS) was 19.3 months (95% CI: 14.23-NE) and 11.9 months (95% CI: 10.74-13.37) for the Benmelstobart in combination with Anlotinib and chemotherapy group and chemotherapy-only group, respectively, and the risk of death was reduced by 39%, with a statistically significant difference. In terms of safety, there were no unanticipated serious adverse events, and the overall safety profile of Benmelstobart in combination with Anlotinib and chemotherapy for the first-line treatment of patients with ES-SCLC was manageable[5].

Lung cancer is a malignant tumour with high incidence and mortality rates in China and worldwide, and small cell lung cancer (SCLC) accounts for 13-17% of all lung cancers[6]. SCLC is different from non-small cell lung cancer. It is more aggressive and has a poorer prognosis, with a 5-year survival rate of less than 5%[7], thus, there is urgent need for effective treatment modalities.

The approval is of great significance to the Group:

Anlotinib Further Expands Indications and Enriches Innovative Product Layout in Oncology Sector

This is the first indication approved for Benmelstobart Injection in China, the sixth indication approved for Anlotinib Hydrochloride Capsules in China, and the first first-line indication approved for Anrotinib Hydrochloride Capsules in China in the field of lung cancer. Previously, five indications had been approved for Anlotinib Hydrochloride Capsules: third-line non-small cell lung cancer, third-line small cell lung cancer, soft tissue sarcoma, medullary thyroid cancer and differentiated thyroid cancer.

Potentially The World's Best-in-Class First-Line Small Cell Lung Cancer Treatment

The results of the ETER701 study showed that Benmelstobart Injection in combination with the Anlotinib Hydrochloride Capsules, carboplatin and etoposide significantly prolonged the mOS in patients with ES-SCLC, with the Benmelstobart in combination with Anlotinib and chemotherapy group achieving a mOS of 19.3 months, which was 7.4 months longer than that of the chemotherapy-only group, and was the treatment regimen with the longest mPFS and mOS in any published data to date[8].

Source:

[1] Zhou, Jun, et al. "Phase Ib study of anlotinib combined with TQB2450 in pretreated advanced biliary tract cancer and biomarker analysis." Hepatology 77.1 (2023): 65-76.

[2] Zhou, Jun, et al. "Anlotinib plus TQB2450 in patients with advanced refractory biliary tract cancer (BTC): An open-label, dose-escalating, and dose-expansion cohort of phase Ib trial." (2021): 292-292.

[3] Lan, Chunyan, et al. Anlotinib in combination with TQB2450 in patients with platinum-resistant or platinum-refractory ovarian cancer (ACTION): a multicenter, single-arm, open-label, phase 1b trial.(2021).

[4] Wang, Jiayu, et al. A phase Ib study of TQB2450 plus anlotinib in patients with advanced triple-negative breast cancer. (2021): 1074-1074.

[5] Cheng Y, Yang R, Chen J, et al. Benmelstobart with anlotinib plus chemotherapy as first-line therapy for ES-SCLC: a randomized, double-blind, phase III trial (ETER701). Presented at: 2023 World Lung Cancer Conference; September 9-12, 2023; Singapore, Republic of Singapore. OA01.03.

[6] Chinese Society of Clinical Oncology (CSCO) Small Cell Lung Cancer Treatment Guidelines (2023).

[7] Cheng Y. Small Cell Lung Cancer [M]. People's Medical Publishing House Co., Ltd. (2014).

[8] Benmelstobart Ups ES-SCLC Survival. Cancer Discov. 2023 Nov 1;13(11):2296-2297.

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

Hong Kong, 9 May 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.