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
APPLICATION FOR CLINICAL TRIAL OF "TQB6411 (EGFR/C-MET BISPECIFIC ADC)" ACCEPTED BY CDE

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the application for clinical trial of the Group's self-developed "TQB6411 (EGFR/c-Met bispecific ADC)" has been submitted to and accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China.

Epidermal growth factor receptor (EGFR) and cell mesenchymal epithelial transition factor (c-Met) are two important lung cancer driver genes. Both belong to receptor tyrosine kinases and have a synergistic effect on downstream signal transduction[1,2]. Combined targeting of EGFR and c-Met can simultaneously block the PI3K/AKT/mTOR and Ras/Raf/Mek pathways and enhance anti-tumour effects by inhibiting compensatory activation[3].

TQB6411 is an antibody-drug conjugate (ADC) targeting EGFR and c-Met. After intravenous injection into the blood, its antibody part binds to EGFR and c-Met on the surface of tumour cells to block the EGFR and c-Met signaling pathways. The ADC is then endocytosed and transported to lysosomes, where the linker is enzymatically cleaved to release DDDXD, resulting in DNA damage and cell death. In vitro studies have shown that TQB6411 has antibody-dependent cell-mediated cytotoxicity (ADCC), and DDDXD can kill surrounding tumuor cells through the bystander effect.

TQB6411 has completed systematic pharmacological, pharmacokinetic and safety verifications. With a clear anti-tumour mechanism, it has significant tumour-suppressive effects on positive cells with different expression levels of EGFR and c-Met and different resistance levels. Its in vitro activity is comparable to that of AZD9592, which has the same targets, while its in vivo activity is significantly better than that of AZD9592.

In addition to TQB6411, the Group has other drugs targeting EGFR and c-Met in the pipeline, including TQB2922 (EGFR/c-Met bispecific), which has initiated a Phase I clinical study in December 2023, TQB3002 (fourth-generation EGFR inhibitor), which is in Phase I clinical development and has been approved for clinical trial in the United States, and FHND9041 (third-generation EGFR inhibitor), which is in Phase III clinical development. The Group will expedite the clinical development of these products and focus on unmet clinical needs around the world, with a view to providing patients with better treatment options.

Sources:

[1] Garraway LA. Genomics-driven oncology: Framework for an emerging paradigm. J Clin Oncol. 2013;31(15):1806–1814.

[2] Puri N, Salgia R. Synergism of EGFR and c-Met pathways, cross-talk and inhibition, in non-small cell lung cancer. J Carcinog. 2008;7(1):9.

[3] Wang J, Chi Y, Chen H, Jia B, Zhai X, Ma M, Li J, Zhuo M. Analysis of the Efficacy and Safety of Amivantamab in Non-small Cell Lung Cancer Patients with EGFR/MET Gene Abnormalities: A Single Center's Experience. Zhongguo Fei Ai Za Zhi. 2022 Jul 20;25(7):493-500.

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

Hong Kong, 3 April 2025

As of 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.