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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 "TQB2101 (ROR1 ADC)" APPROVED BY NMPA

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the Group's self-developed "TQB2101 (ROR1 ADC)" has been given implied approval for clinical trial by the National Medical Products Administration (NMPA) of China. The drug is intended for use in the treatment of advanced malignant tumours.

Receptor tyrosine kinase-like orphan receptor 1 (ROR1) is a transmembrane protein in the type I receptor tyrosine kinase family. It has a low level of expression in normal adult tissues but a high expression in various malignant tumours including hematological malignancies, lung cancer, pancreatic cancer, breast cancer, colorectal cancer and ovarian cancer¹. A study showed that the malignancy and invasion of tumour cells were closely associated with the expression level of ROR1².

Preclinical data showed that TQB2101 demonstrated anti-tumour activity in various ROR1-positive tumour models and had a good safety profile. The approved Phase I clinical trial will focus on evaluating its safety, tolerability, pharmacokinetics and preliminary efficacy in humans.

With the addition of TQB2101, the Group now has a total of four antibody-drug conjugates (ADCs) in clinical stage. Among them, TQB2102 (HER2 bispecific ADC) is in Phase III clinical development, TQB2103 (Claudin 18.2 ADC) is in Phase I clinical development, and TQB6411 (EGFR/c-Met bispecific ADC) is in the clinical application stage. The Group will expedite their clinical development and, leveraging its self-developed ADC technology platform, develop more innovative drugs, with a view to building a healthier world with science.

Sources:

- [1] Shen Wangxun, Yang Yinyu, Li Canwei, Yang Jinrong, Wu Sijing, Zhao Huajun, Tuo Xiaoyu. Expression and clinical significance of ROR1 in invasive lung adenocarcinoma of different histological grades[J]. Journal of Kunming Medical University, 2024, 45(5): 60-65.
- [2] Zhang S, Chen L, Cui B, et al. ROR1 is expressed in human breast cancer and associated with enhanced tumor-cell growth[J]. PLoS One,2012,7(3): e31127. doi: 10.1371/journal.pone.0031127

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.