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
INCLUSION OF TQ-B3234 "SELECTIVE MEK1/2 INHIBITOR" IN THE BREAKTHROUGH THERAPY DESIGNATION PROCESS

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that TQ-B3234 capsule "selective MEK1/2 inhibitor", a national Class 1 new drug developed primarily by the Group, has been included in the Breakthrough Therapy Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China for the treatment of adult plexiform neurofibromas associated with symptomatic and inoperable neurofibromatosis type I (NF1).

TQ-B3234 is a selective MEK1/2 inhibitor. MEK is an upstream mediator of the extracellular signal-associated kinase (ERK) pathway, and MEK inhibitors are able to inhibit tumor growth by inhibiting RAS-mediated RAF/MEK/ERK pathway activity.

Previously, the Group announced the Phase I clinical (TQ-B3234-I-02) trial results of TQ-B3234 at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting[1]: TQ-B3234 showed significant activity against NF1-associated plexiform neurofibroma (PN) and cutaneous neurofibroma (cNF). Among them, 96.7% of NF1-PN subjects had tumor shrinkage, 36.7% of subjects achieved partial response (REiNS criteria), and the objective response rate (ORR) continued to rise as the follow-up time extended. In an exploratory analysis of 6 cNF patients, all patients (100%) had tumor shrinkage, with a maximum shrinkage of 85.2%. TQ-B3234 has demonstrated good tolerability in adult patients with NF1. The latest research progress suggests that the efficacy and tolerability of TQ-B3234 may continue to improve with the extension of treatment time, and the detailed information will be officially announced at the forthcoming academic conference.

NF1 is an autosomal dominant disorder caused by mutations in the NF1 gene, accounting for approximately 96% of all neurofibromatosis, with an estimated incidence of 5 per million in Chinese newborns [2], and was included in China's Second Batch of Rare Diseases Catalogue in September 2023. Among them, approximately 30%-60% of NF1 patients will develop into PN, leading to pain, disfigurement, and even malignant transformation. Currently, a surgery is the main treatment method, but it faces challenges such as high difficulty and easy recurrence.

According to the 2025 Expert Consensus on the Full-course Disease Management of Plexiform Neurofibroma, for inoperable patients, MEK inhibitors for targeted therapy are preferred to control the disease. MEK inhibitors have been proven to be effective in pediatric patients and have been approved for marketing in China, but there is still a lack of effective treatment drugs for adult PN patients in China, and the treatment needs are significantly unmet.

The phase III registered clinical study of TQ-B3234 for the treatment of adult PN has been approved by the CDE. The study aims to confirm its efficacy and safety in a larger patient population to fill the gap in domestic treatment. The inclusion of TQ-B3234 in the BTD will accelerate the drug launch process and is expected to early benefit more patients.

Source:

[1] Jun Liu, Qingfeng Li, Zhichao Wang, et al. An open-label phase 1 dose-escalation and dose-expansion trial to evaluate the safety, tolerability, and efficacy of TQ-B3234 in adults with neurofibromatosis type 1(NF1). 2025 ASCO (#3108).

[2] National database of the National Bureau of Statistics

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

Hong Kong, 15 October 2025

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.