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
NEW INDICATION OF TDI01 SUSPENSION ("ROCK2 INHIBITOR") INCLUDED IN BREAKTHROUGH THERAPY DESIGNATION PROCESS BY CDE

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 Class 1 innovative drug TDI01 suspension, a "ROCK2 inhibitor", 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. The drug is used for the treatment of moderate to severe chronic graft-versus-host disease (cGVHD) in patients who have received at least 1 prior line but no more than five prior lines of systemic therapy.

TDI01 is an innovative, oral, highly selective ROCK2 inhibitor and the first ROCK2 inhibitor domestically developed in China. TDI01 can effectively inhibit pro-inflammatory Th17 cells, promote regulatory T cells, and restore immune homeostasis. The ROCK2 inhibitor can also act directly on ROCK2 targets in fibroblasts, blocking the differentiation of fibroblasts into myofibroblasts and inducing the apoptosis of existing myofibroblasts, thereby achieving a dual mechanism of restoring immune homeostasis and reversing fibrosis.

Results from a Phase Ib/II clinical study demonstrated that TDI01 exhibited significant efficacy potential and good safety in patients with moderate to severe cGVHD who had received 1-5 prior lines of treatment[1]. The results were presented orally at the 51st Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2025).

cGVHD is one of the major complications following allogeneic hematopoietic stem cell transplantation, with an incidence of 30-70%[2]. In patients surviving beyond five years, the incidence of cGVHD exceeds 50%. The pathogenesis of cGVHD is complex, with diverse clinical manifestations, significant individual variability, and a prolonged course of disease. Without standardized treatment, it may severely impair patients' quality of life and even threaten long-term survival[3].

In addition to cGVHD, TDI01 has been approved for clinical trials in China for the treatment of idiopathic pulmonary fibrosis, pneumoconiosis, and liver fibrosis. The Group will spare no effort in advancing the clinical development of TDI01, with a view to providing patients with more innovative treatment options that are both safe and effective.

Sources:

[1] Mo X, Zhang X, Guo R, et al. TDI01 in the treatment of moderate to severe chronic graft-versus-host disease: Results from a multicenter, open-label phase Ib/II study. Presented at: 51th Annual EBMT Meeting; March 30-April 2, 2025. Florence, Italy. Abstract GS2-8.

[2] 王筱淇，張曦.《慢性移植物抗宿主病 (cGVHD) 診斷與治療中國專家共識(2024年版)》解讀[J].臨床血液學雜誌, 2024, 37(9):597-601.

[3] Hematopoietic Stem Cell Application Group, Chinese Society of Hematology, Chinese Medical Association; China Association for the Prevention of Hematology Diseases. [Chinese consensus on the diagnosis and management of chronic graft-versus-host disease (2021)]. Zhonghua Xue Ye Xue Za Zhi. 2021 Apr 14;42(4):265-275. Chinese.

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

Hong Kong, 16 June 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.