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SINO BIOPHARMACEUTICAL LIMITED 中國生物製藥有限公司

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VOLUNTARY ANNOUNCEMENT ROVADICITINIB TABLET "JAK/ROCK INHIBITOR" INCLUDED IN THE BREAKTHROUGH THERAPEUTIC DESIGNATION PROCESS

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that Rovadicitinib Tablet "TQ05105 (JAK/ROCK inhibitor)" independently developed by the Group has been included in the Breakthrough Therapeutic Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China for the treatment of chronic graft-versus-host disease (cGVHD).

Rovadicitinib is the world's fastest-progressing dual JAK/ROCK small-molecule inhibitor in terms of research and development (R&D) progress. The Group submitted the application for marketing in respect of rovadicitinib to the CDE and the application was accepted in July 2024, for the treatment of moderate and high-risk myelofibrosis (MF). Currently, rovadicitinib is undergoing Phase III clinical trials for cGVHD in China and has been approved for Phase II clinical trials in the United States.

Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is an effective treatment for malignant haematological diseases, and chronic graft-versus-host disease (cGVHD) is one of the major complications of allo-HSCT, with an incidence of up to 30%-70%^[1]. The results of the Phase Ib/IIa clinical trial of rovadicitinib have been published in Blood, a leading international journal in the field of haematology: The study enrolled a total of 44 subjects suffering moderate or severe glucocorticoid-refractory or glucocorticoid-dependent cGVHD. No dose-limiting toxicity was observed, and no adverse events related to rovadicitinib leading to discontinuation occurred. The best overall response (BOR) was 86.4%, and the 12-month failure-free survival (FFS) was 85.2%. 88.6% of subjects reduced their need for glucocorticoid dose, and 59.1% of subjects experienced improvement in cGVHD-related symptoms^[2].

Currently, the Phase III clinical trial of rovadicitinib for the treatment of moderate to severe cGVHD is in the process of subject recruitment. The Group will accelerate the R&D of rovadicitinib globally to bring a better treatment solution to patients worldwide as soon as possible.

Sources:

- [1] Xu Shuwei, Man Yan, Zhao Jinlian, et al. Pathogenesis and Treatment Prospects of Chronic Graft-Versus-Host Disease [J]. Journal of Experimental Hematology, 2024,32(02):647-652.
- [2] Zhao YM, Luo Y, Shi JM, Wang SQ, Wang CK, Jiang EL, Liang C, Zhu XY, Zhang XJ, Meng FK, Jin H, Zhao YQ, Yu J, Lai XY, Liu LZ, Fu HR, Ye YS, Zhang CX, Wang T, Tu LF, Wang XQ, Huang H. A first-in-class JAK/ROCK inhibitor, rovadicitinib, for glucocorticoid-refractory or -dependent chronic GVHD. Blood. 2025 Jun 12;145(24):2857-2872.

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

Chairwoman

Hong Kong, 6 August 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.