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)

RESULTS FROM PHASE IB/IIA CLINICAL STUDY OF FIRST-IN-CLASS JAK/ROCK INHIBITOR "ROVADICITINIB" PUBLISHED IN *BLOOD*

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the results of a Phase Ib/IIa clinical study of "Rovadicitinib", a National Class 1 innovative drug self-developed by the Group for the treatment of chronic graft-versus-host disease (cGVHD), have been published in *Blood* (IF: 21.0), a leading international journal in the field of hematology.

Rovadicitinib is the world's first oral, small-molecule JAK/ROCK inhibitor with dual inhibition mechanisms, targeting JAK1/2 and ROCK1/2 with dual anti-inflammatory and anti-fibrotic effects. The drug has demonstrated therapeutic potential in the treatment of cGVHD, myelofibrosis, and hemophagocytic syndrome.

Methods

The study was an open-label, multicenter Phase Ib/IIa clinical study (NCT04944043) conducted in China to evaluate the safety and efficacy of rovadicitinib in the treatment of glucocorticoid-refractory or -dependent cGVHD.

Results[1)]

A total of 44 subjects were enrolled in the study, with 29 in a 10 mg twice-daily group and 15 in a 15 mg twice-daily group. The results showed that rovadicitinib was well tolerated, with no dose-limiting toxicity at both dosages and no rovadicitinib-related adverse events leading to discontinuation. The most prevalent hematological adverse event was anemia (38.6%, with grade ≥ 3 of 4.6%).

The best overall response (BOR) for the overall study population was 86.4% (95% confidence interval (CI), 72.6-94.8), with no difference between the two dosage groups. Besides, BOR achieved 72.7% (8/11) in the glucocorticoid-refractory cohort and 90.9% (30/33) in the glucocorticoid-dependent cohort. All affected organs exhibited responses regardless of any prior therapy. The failure-free survival rate for 12 months was 85.2% (95% CI, 64.5-94.3). Rovadicitinib treatment reduced the glucocorticoid dose in 88.6% of subjects. cGVHD-related symptoms were improved in 59.1% of subjects.

Rovadicitinib demonstrated notable clinical response rates and favourable tolerability in the cGVHD population, improving the quality of life and reducing glucocorticoid dose requirements in patients with glucocorticoid-refractory or -dependent cGVHD.

Significance

JAK and ROCK are two key signaling pathways that regulate immune response and fibrotic progression. With its world-first dual inhibition mechanisms, rovadicitinib can simultaneously block abnormal immune activation and fibrotic progression. It demonstrated excellent disease control in cGVHD patients, providing them with a safe and effective therapeutic option. The publication of the study in such a prestigious journal as *Blood* has confirmed the scientific value of the drug, which will become a new treatment option for cGVHD patients.

The Group submitted a marketing application for rovadicitinib for the treatment of moderate- and high-risk myelofibrosis to the Center for Drug Evaluation of the National Medical Products Administration of the People's Republic of China in July 2024 and initiated a Phase III clinical trial of rovadicitinib for the treatment of moderate to severe cGVHD in October 2024. In addition, the Group obtained approval from the U.S. Food and Drug Administration (FDA) in January 2025 to conduct a Phase II clinical trial of rovadicitinib for the treatment of cGVHD in the United States. The Group will accelerate the global clinical development of rovadicitinib and expedite the launch of the product to fill the clinical gap for the benefit of patients.

Source:

[1] Zhao Y, Luo Y, Shi J, et al. A First-in-Class JAK/ROCK Inhibitor Rovadicitinib for Glucocorticoid-Refractory or -Dependent Chronic GVHD[J]. Blood, 2025.

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

Hong Kong, 10 March 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.