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
"ROVADICITINIB TABLET" APPROVED FOR MARKETING

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the rovadicitinib tablet (Trade name: Anxu (安煦®)), a national Category 1 innovative drug independently developed by the Group, has been approved by the National Medical Products Administration (NMPA) of China for marketing. It is indicated for the first-line treatment of adult patients with intermediate-2 or high-risk primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF).

Rovadicitinib is a global first-in-class small-molecule inhibitor that targets both JAK/ROCK. By leveraging the synergistic effects of the dual JAK/ROCK pathways, it achieves dual therapeutic effects of anti-inflammation and anti-fibrosis. Rovadicitinib, on one hand, inhibits the JAK1/2–STAT3/5 signaling pathway to minimize high-level inflammatory cytokines produced by myeloid cells, thereby exerting anti-inflammatory effects that alleviate splenomegaly and systemic symptoms. On the other hand, by inhibiting ROCK1/2, it lowers the polarization level of helper T cells and the pro-inflammatory cytokine load in patients with myelofibrosis, which further enhances the anti-inflammatory effect while supporting the long-term disease control.

In a multicenter, randomized, double-blind, double-simulation, positive drug-parallel controlled Phase II clinical study (TQ05105-II-01), rovadicitinib demonstrated superior efficacy and showed a favorable safety profile compared to hydroxyurea in treating patients with intermediate-2 or high-risk myelofibrosis. A total of 107 patients were enrolled in the study and randomized in a 2:1 ratio to receive either 15 mg of rovadicitinib or 0.5 g of hydroxyurea orally twice daily.

In terms of efficacy, in the rovadicitinib group, 58.33% of patients achieved a ≥35% reduction in spleen volume (SVR35) at Week 24 compared with baseline as assessed by the independent radiology review committee (IRC), 63.89% of patients achieved SVR35 at any time point, with an average SVR35 duration of 8.31 months. The best ≥50% reduction in total symptom score (TSS50) rate was 77.78% in the rovadicitinib group. In terms of safety, rovadicitinib was generally well-tolerated. In relevant studies, the incidence of Grade≥3 adverse events was approximately 40%, with the incidence of anemia being approximately 40%, and the treatment discontinuation rate being merely 6.7%, all of which were significantly lower than those observed with ruxolitinib.

Myelofibrosis (MF) is a rare myeloproliferative neoplasm clinically characterized by progressive cytopenias, hepatosplenomegaly, and systemic symptoms such as fatigue, night sweats, and bone pain, along with an increased risk of progression to acute myeloid leukemia[1]. With the intensified trend of aging population, the number of patients with MF in China has shown a continuous uptrend. In 2025, there were more than 67,000 patients and the number of patients is projected to reach approximately 300,000 by 2030. Due to the features such as insidious onset and complex symptoms, most patients are already at an intermediate or advanced stage when being diagnosed, resulting in a significant disease burden. Currently, there is no curative treatment for MF, and the clinical therapy primarily focuses on relieving symptoms, delaying disease progression, and improving the quality of life. With its dual therapeutic effects of anti-inflammation and anti-fibrosis, rovadicitinib is expected to act as a breakthrough treatment option for patients with MF, thereby reshaping the clinical treatment landscape.

Beyond MF, rovadicitinib has also demonstrated breakthrough potential in the treatment of chronic graft-versus-host disease (cGVHD). Currently, the development of rovadicitinib for cGVHD is progressing smoothly: in China, it has advanced to the Phase III clinical trial stage and was included in the Breakthrough Therapy Designation (BTD) process by the Center for Drug Evaluation (CDE) of the NMPA in August 2025; in the United States, it has been approved to conduct Phase II clinical studies.

Source:

[1] MESA R A, VERSTOVSEK S, CERVANTES F, et al. Primary myelofibrosis (PMF), post polycythemia vera myelofibrosis (post-PV MF), post essential thrombocythemia myelofibrosis (post-ET MF), blast phase PMF (PMF-BP): Consensus on terminology by the international working group for myelofibrosis research and treatment (IWG-MRT) [J]. Leuk Res, 2007, 31(6): 737-740.

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

Hong Kong, 2 March 2026

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.