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
"RECOMBINANT HUMAN COAGULATION FACTOR VIIA N01 FOR INJECTION" APPROVED FOR MARKETING

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 "Recombinant Human Coagulation Factor VIIa N01 for Injection" (brand name: Anqixin®) has been approved for marketing by the National Medical Products Administration of China. The drug is used for the treatment of bleeding in adult and adolescent (12 years of age and older) patients with congenital hemophilia whose inhibitors to coagulation factor VIII or IX exceed 5 Bethesda units (BU). Anqixin is the first domestically produced recombinant human coagulation factor VIIa-type biological product approved for marketing in China.

The number of hemophilia patients worldwide has been growing steadily. Statistical data indicates that there were approximately 836,000 hemophilia patients worldwide, with approximately 284,000 classified as severe cases [1]. The incidence of inhibitors in severe hemophilia A patients is approximately 30%, that in non-severe hemophilia A patients is 3-13%, and that in hemophilia B patients is 1-6% [2]. The presence of antibodies can lead to poor efficacy of traditional replacement therapy and severely impair patients' quality of life. Recombinant human coagulation factor VIIa, due to its highly effective hemostatic action and unique bypass effect, has become an important treatment option for patients with inhibitors [3] and has been widely used globally.

Anqixin is currently the only recombinant human coagulation factor VIIa in China that has been confirmed for efficacy and safety through a Phase III clinical trial. Its approval is based on a multicenter, single-arm, open-label Phase III clinical study evaluating efficacy and safety in hemophilia patients with inhibitors. The study enrolled 60 subjects, all of whom had received at least one dose of the investigational drug, with 53 subjects experiencing a total of 559 bleeding episodes. An analysis of 551 evaluable bleeding episodes showed a hemostatic efficacy rate of 88.93% (95% CI 86.01, 91.43).

In terms of production processes, recombinant human coagulation factor VIIa poses challenges including a complex structure, numerous degradation and oxidation sites, and a wide variety of impurities. The Group has innovatively developed proprietary processes for cell culture, separation and purification, and formulation, and has obtained two original patents, namely "Purification Method for Human Coagulation Factor VIIa (ZL202010330060.5)" and "Pharmaceutical Composition of Recombinant Human Coagulation Factor VIIa (ZL202410278314.1)". The Group has successfully carried out multiple batches of scaled-up commercial production, with good quality consistency between the batches, thus fully demonstrating the robustness of its production processes.

As the first domestically produced recombinant human coagulation factor VIIa product for injection approved in China, Anqixin will provide patients with a more economical and high-quality treatment option. Previously, the Group's recombinant human coagulation factor VIII for injection (brand name: Anhengji®) had been approved for marketing. Through the combination regimen of Anhengji and Anqixin, the Group will address a full spectrum of treatment needs, from routine replacement therapy to inhibitor management, with a view to benefiting a broader population of hemophilia patients.

Sources:

[1] World Federation of Hemophilia Report on the Annual Global Survey 2023

[2] Thrombosis and Hemostasis Group, Chinese Society of Hematology, Chinese Medical Association; Hemophilia Treatment Center Collaborative Network of China. Chinese guidelines on the diagnosis and treatment of coagulation factor VIII/IX inhibitors (version 2018)[J]. Zhonghua Xue Ye Xue Za Zhi. 2018 Oct 14;39(10):793-799.

[3] Yu DD, Liu W, Zhang L. Pathophysiology, diagnosis, and therapy for the management of acquired clotting factor deficiency. Zhonghua Xue Ye Xue Za Zhi. 2023 Nov 14;44(11):956-962.

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

Hong Kong, 3 July 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.