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# 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 APPLICATION FOR MARKETING OF TQG203 "RECOMBINANT HUMAN COAGULATION FACTOR VIIa FOR INJECTION" FILED AND ACCEPTED

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the application for marketing of TQG203 "Recombinant Human Coagulation Factor VIIa for Injection" developed by the Group has been filed with and accepted by the National Medical Products Administration of China. Its indications are the treatment of bleeding in patients with inhibitor-positive congenital hemophilia A or B as well as certain groups of patients with specific types of rare bleeding disorders and the prevention and treatment of bleeding in surgical or invasive operations.

#### **Clear Mechanism of Action**

Recombinant Human Coagulation Factor VIIa for Injection contains activated recombinant coagulation factor VIIa, which can bind with tissue factor to activate coagulation factor X to become coagulation factor Xa, trigger the conversion of prothrombin to thrombin, and thus form thrombus. Coagulation factor VIIa also activates coagulation factor IX to become coagulation factor IXa, which further increases the formation of thrombus. For localized vascular wall damage, coagulation factor VIIa forms a complex with tissue factor/phospholipid, which is in an activated state, and lead to hemostasis.

## Extremely High Technical Difficulty, Potentially First Domestic Product Approved for Marketing

The preparation process of Recombinant Human Coagulation Factor VIIa for Injection is extremely complicated, and the technical barrier is extremely high. Therefore, there is no similar domestic product in the China market at present. The molecular structure of Recombinant Human Coagulation Factor VIIa for Injection is composed of 406 amino acids in a light chain and a heavy chain, with O and N glycosylated structures, and  $\gamma$  carboxylation of glutamic acid at the N-terminal of the heavy chain.

### **Substantial Marketing Potential**

The number of congenital hemophiliacs worldwide is increasing year by year. In 2021, the number of hemophiliacs worldwide was nearly 450,000, and it is expected that the number will increase by another 25% in 2025. The inhibitor positivity rate of hemophiliacs is about 4%, and the lack of effective treatments has a serious impact on the quality of life of the patients. Recombinant human coagulation factor VIIa has significant hemostatic effect, and its application has become more and more popular.

TQG203 is expected to break the monopoly of brand-name drugs and become the first domestic recombinant human coagulation factor VIIa for injection product approved for marketing in China, providing more treatment options for hemophiliacs in China. Recombinant Human Coagulation Factor VIII for Injection developed by the Group was already approved for marketing in August 2023. In the future, the Group will continue to promote the layout of its drug portfolio to cover the needs of hemophiliacs patients more comprehensively, address the unmet clinical needs, and benefit more families.

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

Hong Kong, 13 December 2023

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin 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.