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
FIRST DOSE OF THE FIRST BATCH OF SUBJECTS IN PHASE I CLINICAL TRIAL OF TQA3038 "siRNA" COMPLETED

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group is conducting "a randomized, double-blind, placebo-controlled Phase I clinical trial for evaluating the safety, tolerability and pharmacokinetic characteristics of TQA3038 in healthy adult subjects". TQA3038 is a small interfering RNA (siRNA) drug that targets the hepatitis B virus (HBV), developed by the Group for the treatment of chronic hepatitis B (CHB). The first-in-human clinical trial of TQA3038 has recently completed the enrollment of the first batch of subjects, and the dosing process went smoothly with post-dose observations completed.

Chronic hepatitis B is a severe public health issue worldwide, with approximately 290 million people globally suffering from chronic infection. China is a high-prevalence area for hepatitis B with an estimate of around 86 million people with HBV infection, indicating a significant need for treatment among the population. Of CHB patients who have not received effective treatment, 15-40% is subject to the risk of progression to liver cirrhosis, liver decompensation or even liver cancer. Current treatment methods include nucleoside analogues (NAs) and interferon, but it is challenging to achieve a functional cure, necessitating the development of effective therapies. The current consensus among both domestic and overseas experts is to aim for a functional cure of HBV, which is defined as sustained clearance of HBsAg and HBV DNA in the blood serum after treatment for a limited period. However, HBsAg reduction remains a key challenge in clinical treatment.

As a GalNAc-conjugated siRNA drug, TQA3038 can accumulate in the liver and effectively degrade the targeted RNA, inhibiting the translation of relevant proteins and thereby blocking the replication of the HBV. It is expected to significantly improve the functional cure rate in clinical settings. TQA3038 utilizes nucleic acid sequences with independent intellectual property rights and exhibits stronger in vivo and in vitro antiviral activities compared with siRNA which has made the fastest progress in clinical development. Non-clinical studies have shown that TQA3038 can highly inhibit infection markers in AAV-HBV model mice and demonstrate good safety and tolerability in rat and cynomolgus monkey toxicology trials, indicating a wide safety margin.

The successful enrollment of the first batch of subjects marks the official launch of this clinical study, and the TQA3038 injection has the potential to become the cornerstone of functional cure for hepatitis B, and provide a new treatment option for a vast number of patients.

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

Hong Kong, 5 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.