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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 UPDATE ON DEVELOPMENT PROGRESS OF MASH PRODUCTS "LANIFIBRANOR" AND "TQA2225"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announced that "Lanifibranor" (pan-PPAR agonist) and "TQA2225" (recombinant human FGF21-Fc fusion protein), jointly developed by the Group, are currently undergoing Phase III and Phase II clinical trials, respectively, in China for the treatment of metabolic dysfunction-associated steatohepatitis ("**MASH**").

## About Lanifibranor: Subject Enrollment for International Phase III Clinical Trials Resumed

Lanifibranor (pan-PPAR agonist) is an orally-available small molecule drug that acts to regulate antifibrotic, anti-inflammatory pathways in the body by activating three peroxisome proliferator-activated receptor ("**PPAR**") isoforms. In the NATIVE Phase IIb study, Lanifibranor achieved primary and key secondary endpoints in treating F1-F3 MASH patients, including MASH improvement without worsening of fibrosis, and fibrosis improvement without worsening of MASH. The results of this study have been published in The New England Journal of Medicine. Lanifibranor is the first oral drug candidate to achieve statistically significant results on both key clinical endpoints recommended by the U.S. Food and Drug Administration ("**FDA**") and the European Medicines Agency (EMA). FDA has granted Lanifibranor breakthrough therapy designation and fast track status for MASH.

In March 2023, a clinical trial application of Lanifibranor was submitted to the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration of China and received acceptance. In July, Lanifibranor was included in the list of breakthrough therapeutic category by the CDE. Currently, Phase III clinical trials on Lanifibranor are being conducted globally for the treatment of F2/F3 MASH patients. The collaborator of the Group, Inventiva, announced on 7 March 2024 the resumption of international subject enrollment for Phase III clinical trials of Lanifibranor and expects to complete all subject enrollments in 2024.

Lanifibranor is the first oral drug for MASH to enter Phase III clinical trials in China. The Group will accelerate clinical research and development efforts to fill the gap in China's MASH market as soon as possible.

## About TQA2225: Progress of Phase II Clinical Trials Accelerated

TQA2225 is a fully human long-acting fibroblast growth factor 21 ("**FGF21**") fusion protein. Compared with other similar targeted drugs, TQA2225 adopts pure natural human FGF21 as the active form, which reduces potential immunogenicity and demonstrates good safety profile. In addition, TQA2225 utilizes a unique linker platform technology to extend the in vivo half-life of FGF21 while preserving its biological activity, making TQA2225 the world's first fully human long-acting FGF21 fusion protein to enter clinical stage.

Clinical studies have demonstrated that FGF21 signal transduction is able to reserve many features of the MASH pathogenesis, with the potential of reversing fibrosis, reducing liver fat and improving glycemic control. Recently, an overseas biotech company announced Phase IIb clinical data on a drug with the same target. The results indicated that the FGF21 fusion protein can significantly improve liver fibrosis and has the potential to become the best-in-class drug for MASH treatment.

Currently, TQA2225 is undergoing Phase II clinical trials in China for the treatment of MASH. TQA2225 is the fastest-developing product in China among those drugs with the same target, and is expected to be the first FGF21 fusion protein to be marketed in China. The Group will accelerate the enrollment of subjects for TQA2225 in order to strive for an early solution to the unsatisfied needs of patients.

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

Hong Kong, 15 March 2024

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.