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 MARKET LAUNCH OF "OBETICHOLIC ACID TABLETS" 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 market launch of "Obeticholic Acid Tablets" developed by Chia Tai Tianqing Pharmaceutical Group Co. Ltd, a subsidiary of the Group, has been filed with and accepted by the National Medical Products Administration of China. The drug is intended to be used for: 1) the treatment of primary biliary cholangitis ("**PBC**") in adult patients with no cirrhosis or compensated cirrhosis with symptoms of portal hypertension; and 2) in combination with ursodeoxycholic acid ("**UDCA**") for use in patients with poor response to UDCA or patients who are intolerant to UDCA as a single drug. At present, there is no obeticholic acid available in the China market.

Obeticholic acid is a farnesoid X receptor ("**FXR**") agonist, which is currently the only drug approved by European and American countries for second-line treatment of PBC. Obeticholic acid can improve biochemical markers and histological progression in PBC patients with suboptimal biochemical response to UDCA, and has demonstrated clear therapeutic efficacy and clinical benefits for PBC patients.

Obeticholic acid exhibits high selectivity for FXR, with an activation potency 100 times greater than its corresponding endogenous agonist chenodeoxycholic acid[1]. FXR is a nuclear hormone receptor that is expressed in the epithelial cells of the small intestine, hepatocytes, and biliary epithelial cells. The FXR signalling pathway regulates target genes involved in bile acid synthesis, secretion, transport, and absorption processes. In addition, FXR plays a key role in inflammation, metabolic regulation and the development of liver fibrosis.

PBC is a rare autoimmune liver disease that can eventually progress to cirrhosis and liver failure. With the improvement in understanding and clinical diagnosis of PBC, the incidence rate of PBC in China is on the rise, reaching 21.05/100,000 in 2022[2]. Currently, there is no cure for PBC, so the treatment focuses on delaying disease progression and preventing complications. UDCA is a first-line therapeutic treatment for PBC, yet about 40% of patients respond poorly to UDCA treatment[3]. Without treatment intervention, the combined effects of chronic cholestasis and bile duct damage will eventually lead to liver failure and even death for patients. Therefore, there is a clear unmet demand of clinical treatment for PBC patients with poor UDCA efficacy or intolerance to UDCA.

The obeticholic acid tablets developed by the Group adopts a proprietary patent route, with stable synthesis process and good batch reproducibility. The Group obtains precise control of product release through continuous optimization of formulation prescriptions and processes to achieve bioequivalence ("**BE**") in vivo. The Group will accelerate the launch process of the product so as to satisfy the unmet clinical demand for the sake of benefiting more patients.

Notes:

1 *Li, Fei, and Lu, Lungen. Obeticholic Acid Increases the Risk of Liver Injury in Patients with Primary Biliary Cholangitis J, vol. 25(6):566-566. 2020. Chinese Hepatology.*

2 *Lian, Min and Ma, Xiong. Advances and Difficulties in the Diagnosis and Treatment of Primary Biliary Cholangitis, vol. 43(04): 253-256. 2023. Chinese Journal of Digestion.*

3 *Lu, Xing, Li Ting, Sun, XiaoDong, et al. Advances in the Treatment of Primary Biliary Cholangitis, vol. 38(9): 2130-2135. 2022. Journal of Clinical Hepatology.*

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

Hong Kong, 1 February 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.