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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

POSITIVE RESULTS ON PHASE III CLINICAL STUDY OF TQB3454 "IDH1 INHIBITOR" FOR BILIARY TRACT CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Phase III clinical study of TQB3454 "IDH1 inhibitor", a national Category 1 innovative drug independently developed by Chia Tai Tianqing Pharmaceutical Group Co. Ltd. ("**CTTQ**", a subsidiary of the Group) for the treatment of advanced biliary tract cancer with IDH1 mutations, has completed the pre-specified interim analysis. As determined by the Independent Data Monitoring Committee (IDMC), the pre-specified primary endpoints of both progression-free survival (PFS) and overall survival (OS) have been reached. The Group has communicated with the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) in respect of the marketing application for this indication and obtained written approval from the CDE, with the marketing application to be submitted shortly. This is the second globally and the first domestically successful Phase III clinical study of an IDH1 inhibitor in biliary tract cancer.

The TQB3454-III-01 study (NCT05987358) is a randomized, double-blind, placebo-controlled, multicenter Phase III clinical study designed to evaluate the efficacy and safety of TQB3454 tablets in patients with advanced biliary tract cancer harboring IDH1 mutations who have previously failed gemcitabine and fluorouracil-based combination therapies. Results from the interim analysis showed that, compared to the control group, TQB3454 significantly reduced the risk of disease progression or death in patients with advanced biliary tract cancer, while significantly prolonging PFS and OS. The safety data were consistent with the known risk profile, with no new safety signals identified. The Group plans to present detailed data from the study at an authoritative international academic conference this year.

Biliary tract cancer (BTC) mainly includes cholangiocarcinoma and gallbladder cancer, accounting for approximately 3% of all digestive system tumors. In 2021, there were more than 200,000 new cases globally, with an uptrend in terms of incidence[1-2]. BTC is predominantly adenocarcinoma, characterized by high malignancy and extremely poor prognosis, with a 5-year survival rate below 5%[1]. Given its highly invasive nature, most patients are already in the medium or advanced stage at initial diagnosis. Only about 10-20% of patients have the opportunity for curative surgeries, and the postoperative recurrence rate is as high as 60%. IDH1 inhibitors represent a crucial component of precision therapy for biliary tract cancer. However, no drugs targeting this pathway have been approved in China, leaving significant unmet clinical needs.

TQB3454 was included in the Breakthrough Therapeutic Designation process by the CDE in April 2023. The positive results from this Phase III clinical study will further accelerate its market approval process, thus enabling the promising outcome as to offer a novel treatment option for patients with biliary tract cancer expeditiously.

Sources:

[1] 2019 CSCO Consensus on Diagnosis and Treatment of Biliary Tract Tumors
[2] Lei S, Huang G, Li X, Xi P, Yao Z, Lin X. Global Burden, Trends, and Inequalities of Gallbladder and Biliary Tract Cancer, 1990-2021: A Decomposition and Age-Period-Cohort Analysis. Liver Int. 2025 Feb;45(2): e16199.

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

Hong Kong, 12 March 2026

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.