SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sbpgroup.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
ACCEPTANCE OF NEW DRUG APPLICATION FOR TQB3454 TABLET "IDH1 INHIBITOR"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that TQB3454 tablet "IDH1 inhibitor", a national Category 1 innovative drug independently developed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), a subsidiary of the Group, has been submitted to and accepted by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration, for the treatment of advanced biliary tract cancer (BTC) harboring IDH1 mutations. Leveraging its significant clinical benefits, TQB3454 was granted Breakthrough Therapy Designation by the CDE in April 2023, and included in the Priority Review and Approval procedures in May 2026.

TQB3454 is an IDH1 inhibitor independently developed by the Group, capable of specifically inhibiting the enzymatic activity of mutant IDH1, reducing the levels of the downstream oncogenic metabolite 2-HG, reversing the DNA and histones hypermethylation caused by abnormally elevated 2-HG, and restoring normal chromatin structure, thereby prompting mutated cells to return to normal differentiation and growth processes, thereby achieving an anti-tumor effect.

This new drug application is based on a randomized, double-blind, placebo-controlled, multicenter Phase III clinical study (TQB3454-III-01), designed to evaluate the efficacy and safety of TQB3454 in patients with advanced BTC harboring IDH1 mutations who have previously failed treatment with gemcitabine and fluoropyrimidine-based regimens. The study results demonstrated that compared with placebo, TQB3454 significantly reduced the risk of disease progression or death, with both progression-free survival (PFS) and overall survival (OS) significantly prolonged. The safety profile was consistent with the known risk profile, with no new safety signals identified. This is the first domestic Phase III study and second in the world of an IDH1 inhibitor to achieve positive results in biliary tract cancer.

BTC primarily includes cholangiocarcinoma (intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma, and distal cholangiocarcinoma) and gallbladder carcinoma, accounting for approximately 3% of all digestive system tumors. It is predominantly adenocarcinoma, characterized by high aggressiveness and an extremely poor prognosis, with a 5-year survival rate of less than 5%. Globally, the incidence of BTC has been increasing year by year, with the highest rates observed in Asian countries. Among biliary malignancies, IDH1 mutations occur mainly in intrahepatic cholangiocarcinoma, with a mutation rate of approximately 4.9%–20.0% [1].

Currently, no drugs with the same target has been approved for the treatment of BTC in China, leaving a significant unmet clinical need. TQB3454 is expected to fill this gap in the market and provide a novel and highly effective treatment option for patients with IDH1-mutant biliary tract cancer in China.

Source:

[1] Pathology Group of the Committee of Liver Cancer, China Anti-Cancer Association; Liver Pathology Group of the Committee of Tumor Pathology, China Anti-Cancer Association; Committee of Tumor Pathology, Shanghai Anti-Cancer Association. Expert consensus on precision testing for intrahepatic cholangiocarcinoma (2024 edition) [J]. Journal of Clinical Hepatology, 2025, 41(3): 432-441.

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

Hong Kong, 10 July 2026

As at the date of this announcement, the Board of the Company comprises five executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y and Mr. Tse Hsin and six independent non-executive directors, namely Mr. Lu Zhengfei, Ms. Lu Hong, Mr. Zhang Lu Fu, Dr. Li Kwok Tung Donald, Dr. Chen Lieping and Dr. Lu Bai.