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
APPLICATION FOR CLINICAL TRIAL ON IM-101 INJECTION "PRES1 RECOMBINANT FUSION PROTEIN" APPROVED BY THE NMPA

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that IM-101 injection "PreS1 recombinant fusion protein", a national Category 1 innovative drug developed by the Group's subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), has received the approval for clinical trial from China's National Medical Products Administration (NMPA), for the treatment of chronic hepatitis B (CHB).

IM-101 is an innovative recombinant fusion protein targeting PreS1. It has the potential to break immune tolerance and restore hepatitis B virus (HBV)-specific immune responses. PreS1 is a key component of the HBV surface protein, which mediates viral adsorption and invasion by binding to the sodium taurocholate co-transporting polypeptide (NTCP) receptors on the surface of hepatocytes. IM-101 has the potential to induce multiple immune effects: at the level of humoral immunity, PreS1-specific antibodies can directly neutralise viral particles, block their binding to the NTCP receptors, prevent the virus from entering hepatocytes, and reduce HBV reinfection and the replenishment of the viral replication template within the liver; at the level of cellular immunity, IM-101 can activate HBV-specific T-cell responses, thereby clearing virus-infected hepatocytes via both cytolytic and non-cytolytic mechanisms, thereby reducing the viral reservoir. Collectively, these actions position IM-101 as a promising therapeutic strategy toward achieving functional cure of CHB.

CHB remains a major public health challenge worldwide. There are approximately 290 million people with chronic HBV infection worldwide, of whom around 75 million cases are in China. In absence of timely and standardised antiviral treatment, CHB carries a high risk of progression to cirrhosis, liver failure or even hepatocellular carcinoma.

Currently, the treatment of CHB primarily relies on two major types of drugs: nucleos(t)ide analogues (NAs) and interferons. NAs can effectively suppress the replication of HBV DNA, but the rate of hepatitis B surface antigen (HBsAg) clearance is only 0–3% and are associated with high post-treatment relapse, mandating long-term or even lifelong treatment for most patients. Interferons exert both direct antiviral and immunomodulatory effects; however, its response rates vary widely across individuals, with HBsAg seroclearance of only 3-7% in the overall population as monotherapy. Functional cure is defined as sustained serum HBsAg and HBV DNA levels below the lower limit of quantification after a finite course of therapy. Its core objective is to restore durable immune control over HBV, thereby reducing the risk of progression to cirrhosis, hepatocellular carcinoma, and other end-stage liver diseases.

As a leading player in China's liver diseases landscape, the Group focuses on core areas such as the functional cure of CHB, HBV suppression, and metabolic dysfunction-associated steatohepatitis (MASH), with multiple innovative drug candidates advancing into clinical stages. Lanifibranor (pan-PPAR agonist) is currently in a global Phase III clinical trial; TQA3605 (HBV core protein allosteric modulator) has received approval from the Center for Drug Evaluation (CDE) to proceed with Phase III development; and both TQ-A3334 (TLR-7 agonist) and Kylo-0603 (THR- β agonist) are both in Phase II clinical trials. Furthermore, the Group has entered into a strategic collaboration with GSK to jointly accelerate the market launch of Bepirovirsen in China. A marketing application for this drug has been submitted in China and is granted priority review and approval designation, positioning it as a potential global first-in-class innovative drug approved for the functional cure of CHB. IM-101 has further enriched the pipeline layout of the Group in the field of active immunotherapy. The Group will continue to explore both monotherapy and combination regimens across diverse mechanisms of action, aiming to offer a broad spectrum of therapeutic options for a wider range of patients with liver diseases.

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

Hong Kong, 23 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.