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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.sbpgroup.com

(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT

**NALDEMEDINE, “PERIPHERAL μ -OPIOID RECEPTOR ANTAGONIST”,
APPROVED FOR MARKETING IN THE GREATER BAY AREA**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that, Naldemedine, an innovative drug exclusively licensed by the Group’s subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (“**CTTQ**”), was approved by Guangdong Medical Products Administration for an early launch in the Guangdong-Hong Kong-Macao Greater Bay Area for the treatment of opioid-induced constipation (OIC).

In March of this year, the Guangzhou Municipal Health Commission issued the *Notice on Ten Measures to Advance the In-depth Implementation of ‘Hong Kong and Macao Medicine and Equipment Connect’ Policy*, marking the transition of the ‘Hong Kong and Macao Medicine and Equipment Connect’ from the policy exploration to the new stage of large-scale implementation. Naldemedine became one of the first innovative medicines to enter the Greater Bay Area under the ‘Hong Kong and Macao Medicine and Equipment Connect’ following the announcement of the new policy.

Naldemedine is the world's first approved oral selective peripheral μ -opioid receptor antagonist. By blocking the binding of opioid drugs to μ -receptors in the gut, it directly restores normal intestinal motility rhythms and intestinal secretory function, thereby fundamentally reversing the pathological process of OIC^[1]. In a 2-week, randomised, double-blind, placebo-controlled phase 3 study, the median time from the first dose of Naldemedine to spontaneous bowel movement (SBM) in patients with OIC was 4.67 hours, which was significantly superior to the placebo group (26.58 hours, $P < 0.0001$). The SBM response rate in the Naldemedine group was 71.1%, which was significantly higher than that in the placebo group (34.4%, $P < 0.0001$), indicating that 0.2 mg of Naldemedine can effectively control OIC and provide sustained, stable improvement in bowel function.

The incidence of pain in patients with advanced cancer ranges from 60% to 80%, approximately one-third of whom experience moderate-to-severe pain. While opioid drugs remain the primary treatment for cancer patients with chronic pain, 60% to 90% of patients develop OIC, which severely impairs quality of life and treatment adherence^[2]. Consequently, effective management of OIC while balancing analgesia and adverse effects represents a critical clinical challenge. Current therapeutic options exhibit obvious limitations: laxatives provide only symptomatic relief and are associated with gastrointestinal side effects; although naloxone, the traditional opioid receptor antagonist, can mitigate the gastrointestinal effects of opioids to alleviate constipation, it may compromise opioid-mediated analgesia by crossing the blood-brain barrier^[3]. Compared with current therapeutic options, Naldemedine selectively targets intestinal μ -opioid receptors without causing electrolyte disturbances, making it suitable for long-term use. Furthermore, due to its minimal penetration into the central nervous system, it does not appear to interfere with the analgesic efficacy of opioid drugs.

Beyond the Greater Bay Area, Naldemedine has been approved for marketing in the United States, the European Union, Japan, Taiwan (China), Macau (China) and Hong Kong (China). Additionally, leveraging the policies of the Boao Lecheng International Medical Tourism Pilot Zone (博鳌樂城國際醫療旅遊先行區), it has been introduced to Hainan Province as a clinically urgent-need drug. Naldemedine is also recommended by the American Gastroenterological Association (AGA) Guidelines and the European Society for Medical Oncology (ESMO) Guidelines for the treatment of OIC^[4,5]. In January 2025, CTTQ signed an exclusive marketing agreement with Shionogi, granting exclusive marketing rights for Naldemedine in Chinese Mainland. In May 2025, the marketing application for Naldemedine was accepted by China's National Medical Products Administration (NMPA).

The approval of Naldemedine in the Guangdong-Hong Kong-Macao Greater Bay Area will further enhance its accessibility. Leveraging its robust commercialisation capabilities, the Group is committed to making this globally innovative medicine available to more OIC patients across China.

Sources:

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

Hong Kong, 9 April 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.