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 "PERIPHERALLY ACTING μ-OPIOID RECEPTOR ANTAGONIST" APPROVED FOR MARKETING

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that, Naldemedine (generic name: Naldemedine Tosylate Tablets; brand name: 欣璞落®/Symproic®), a Class 1 innovative drug exclusively licensed by the Group's subsidiary Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), has been approved for marketing by China's National Medical Products Administration (NMPA) for the treatment of opioid-induced constipation (OIC) in adults.

Naldemedine is the world's first orally administered peripherally acting selective μ-opioid receptor antagonist approved for marketing. By selectively blocking the binding of opioids to μ-opioid receptors in the gastrointestinal tract, it effectively restores normal colonic peristalsis and intestinal fluid secretion, thereby reversing the underlying pathophysiology of OIC at its source[1]. To date, Naldemedine has been approved in China (including Hong Kong, Macau, and Taiwan), the U.S., the EU, the U.K., and Japan, and is recommended for the management of OIC by the American Gastroenterological Association (AGA) and the European Society for Medical Oncology (ESMO) clinical practice guidelines[2,3].

In patients with advanced cancer, the incidence of pain ranges from 60% to 80%, with approximately one-third experiencing moderate to severe pain. Opioids represent a mainstay of chronic pain management in this population; however, OIC occurs in 60% to 90% of these patients[4], which markedly impairs their quality of life and treatment adherence. Therefore, achieving an optimal balance between effective analgesia and OIC management has emerged as a critical clinical challenge.

Currently, treatment options for OIC primarily consist of symptomatic therapies such as laxatives, which may induce gastrointestinal adverse events including nausea, vomiting, diarrhea, and abdominal pain. Moreover, these agents offer only symptomatic relief without addressing the underlying pathophysiology. Opioid receptor antagonists can relieve constipation by reducing the gastrointestinal effects of opioids; however, their ability to cross the blood-brain barrier may compromise opioid analgesic efficacy[5]. In contrast, naldemedine selectively targets peripheral μ-opioid receptors in the gastrointestinal tract, carries minimal risk of electrolyte disturbances, and is therefore more suitable for long-term use in patients with OIC. Furthermore, naldemedine exhibits negligible central nervous system penetration, and no reduction in opioid-induced analgesia has been observed.

In April 2026, naldemedine received marketing approval from the Guangdong Provincial Medical Products Administration and was first launched in the Guangdong-Hong Kong-Macao Greater Bay Area. The approval by the NMPA offers a novel therapeutic option to enhance the quality of life (QoL) for more patients suffering from OIC, thereby advancing the field of cancer supportive care in China.

Sources:

[1] John M, Edward J, et al. Peripherally Acting u-Opioid Receptor Antagonists for the Treatment of Opioid-Related Side Effects: Mechanism of Action and Clinical Implica-tions.

[2] Seth D.Crockett, Katarina B.Greer, Joel J.Heidelbaugh, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation.Gastroenterology 2019;156:218–226.

[3] N.Katakami, T.Harada2, T.Murata, et al.Diagnosis, assessment and management of constipation in advanced cancer: ESMO Clinical Practice Guidelines. Annals of Oncology 29(Supplement4): iv111-iv125, 2018.

[4] Porta-Sales J, Nabal-Vicuna M, Vallano A, et al. Have we improved pain control in cancer patients? A multicen-ter study of ambulatory and hospitalized cancer patients[J]. J Palliat Med, 2015,18(11):923-932.

[5] Yue Wang, Kui Jiang. Progress in pathological mechanism and therapy of opioid-induced constipation[J]. CHINESE JOURNAL OF CLINICAL ONCOLOGY, 2021, 48(16): 852-857.

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

Hong Kong, 29 May 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.