PRESSRELEASE

SHIONOGI

Notice Regarding Approval of Naldemedine for Opioid-Induced Constipation in China

OSAKA, Japan, May 29, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi" or "the Company") announced that its group company, Shionogi China Co., Ltd. (Head Office: Shanghai, China; Chairman: Hirofumi Nagatome), has received approval from the National Medical Products Administration (NMPA) of China on May 27, 2026, for Naldemedine Tosilate (hereafter "naldemedine" or "the drug"), a treatment for opioid-induced constipation (OIC).

OIC is a common adverse effect associated with the use of opioids for the treatment of conditions such as cancer pain, occurring at a high frequency[1]. Symptoms such as difficulty in defecation and abdominal discomfort may lead to deterioration in patients' quality of life (QOL) and discontinuation or dose reduction of opioid therapy, thereby significantly affecting the continuation of appropriate pain management. Current treatment options for OIC primarily consist of symptomatic therapies such as laxatives; however, these approaches may not provide sufficient relief[2].

Naldemedine is a peripherally acting μ-opioid receptor antagonist discovered by Shionogi. Opioids used for pain management exert their analgesic effects by acting on opioid receptors in the central nervous system; however, they also act on μ-opioid receptors in the gastrointestinal tract, which can lead to constipation. Naldemedine selectively binds to μ-opioid receptors in the gastrointestinal tract and directly addresses the underlying cause of opioid-induced constipation (OIC) without affecting the analgesic effects of opioids. As a result, it improves constipation symptoms and contributes to enhanced patient quality of life (QOL) as well as better pain management.
Naldemedine is recommended as a treatment for OIC in guidelines[3,4] issued by the American Gastroenterological Association (AGA) and the European Society for Medical Oncology (ESMO), and the approval of naldemedine in China is expected to contribute to the treatment of OIC in the country.

This approval is based on favorable results from Phase 3 clinical trials conducted in China and outside China. Naldemedine is already marketed in Japan, the United States, Europe and other regions. In China, the product will be marketed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (Head Office: Jiangsu, China; CEO: Eric Tse), and we will work in collaboration with our partner to promote the broader adoption of this product.

Shionogi has identified "Contributing to a healthier and enriched life" as one of its material issues, and is advancing initiatives to realize a society in which people can live longer, more fulfilling lives. The Company will continue to strive to improve the QOL of patients affected by pain and adverse effects associated with pain management therapies.

About Naldemedine

Naldemedine is a peripherally acting μ-opioid receptor antagonist that binds to μ-opioid receptors in the gastrointestinal tract and counteracts the peripheral effects of opioids, thereby improving OIC. Naldemedine has been approved in Japan, the United States, and Europe, and is marketed under the brand names Symproic®, Rizmoic®, and others.

Overview of the Phase III Clinical Trial in China

This trial was a multicenter Phase 3 trials consisting of a double-blind, placebo-controlled period followed by an open-label extension period. The treatment period comprised two phases: 2-week double-blind, placebo-controlled treatment period and 10-week open-label treatment period. The primary endpoint was the proportion of patients achieving at least three spontaneous bowel movements (SBMs) per week and an increase of at least one SBM per week from baseline. Naldemedine showed a statistically significant improvement compared with placebo.

About Chia Tai Tianqing (CTTQ)

CTTQ is a core subsidiary of China Medical System Holdings, a company listed on the Hong Kong Stock Exchange, and is engaged in the pharmaceutical business in China. The company conducts research, development, manufacturing, and commercialization of pharmaceuticals in China. The company operates multiple sites, including those in Shanghai, Nanjing, and Lianyungang, and has a portfolio covering therapeutic areas such as infectious diseases, respiratory diseases, oncology, and liver diseases. In addition, more than 7,000 medical and sales representatives provide information on pharmaceutical products, and the company undertakes initiatives utilizing its nationwide academic activity network and its experience in the Chinese healthcare market.

For more information, visit https://www.cttq.com/

References

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Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate

and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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