SHIONOGI & CO., LTD.

SHIONOGI ANNOUNCES THAT NALDEMEDINE MET THE PRIMARY ENDPOINT IN ITS FIRST JAPANESE PHASE 3 STUDY FOR THE TREATMENT OF OPIOID-INDUCED CONSTIPATION IN CANCER PATIENTS

Osaka, Japan, June 24, 2015 - Naldemedine, an investigational peripherally acting mu-opioid receptor antagonist (PAMORA) under development by Shionogi & Co., Ltd (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi"), met its primary and key secondary endpoints in a phase III study (COMPOSE IV) for the treatment of opioid-induced constipation (OIC) in adult patients with cancer pain receiving opioid therapy. This is the first Japanese phase III data generated from the COMPOSE program.

The study results showed that naldemedine (0.2 mg tablet given once daily) demonstrated a statistically significant increase in the spontaneous bowel movement (SBM) responder rate compared to placebo over 2 weeks. Naldemedine was generally well-tolerated and mild diarrhea was the only side effect reported in more than 5 % of subjects. No attenuation of opioid analgesic effects was observed.

OIC is one of the most common side effects of opioid therapy, and has a negative impact on the quality of life of patients with cancer pain, leading to such as limitation of in daily activities and, in some cases, discontinuation of opioid therapy. The results of this study encouraged Shionogi to continue to progress the development of naldemedine, with the goal of delivering a new therapeutic option to patients who are suffering from OIC.

About COMPOSE Program

The COMPOSE program is a global comprehensive development program comprised of 7 clinical studies being conducted in patients with OIC with cancer or chronic non-cancer pain.
COMPOSE IV is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study which was conducted in Japan. The study was designed to evaluate the efficacy and safety of naldemedine therapy, versus placebo, in 193 patients receiving chronic opioid therapy for cancer pain and who are experiencing OIC.

About Opioid Induced Constipation (OIC)

OIC is characterized by any of the following occurring during chronic opioid therapy: reduced bowel movement frequency, development or worsening of straining, a sense of incomplete rectal evacuation, or harder stool consistency.[1] It is estimated that 40-50% of chronic opioid patients experience opioid-induced constipation (approximately 30 million globally), with fewer than half reporting satisfactory results with laxatives.[2] Managing OIC and its clinical consequences places a significant financial burden on the healthcare system and reduces the patient's quality of life.

[1] Camilleri. M, Drossman D.A., Becker G.,Webster L.R., Davies A.N., Mawe G.M. Emerging treatments in neurogastroenterology: a multidisciplinary working group consensus statement on opioid-induced constipation. Neurogastroenterology Motil. 2014. 26, 1386-1395

[2] Pappagallo M. Incidence, Prevalence, and Management of Opioid Bowel Dysfunction. The American Journal of Surgery. 182 (Suppl to November 2001) 11s-18s

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, unavailability 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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