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Shionogi's constipation medicine proves effective in trials

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Tokyo: Shionogi, one of Japan's century-old pharmaceutical manufacturers, has announced that its once-daily naldemedine met primary and secondary endpoints in a phase III study (COMPOSE II) for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

Naldemedine is an investigational, oral, peripherally acting mu-opioid receptor antagonist (PAMORA). This is the third phase III trial in which naldemedine met its primary and key secondary endpoints.

Study results showed that a 0.2 mg tablet of naldemedine given once daily significantly improved the frequency of spontaneous bowel movement (SBM) compared with placebo over 12 weeks. Naldemedine was generally well-tolerated with the most commonly reported side effects being gastrointestinal disorders.

The company explained that the COMPOSE program is a global comprehensive development program comprised of seven clinical studies being conducted in patients with OIC with cancer or chronic non-cancer pain.

COMPOSE II is a 12-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. The study was designed to evaluate the efficacy and safety of naldemedine therapy, versus placebo, in 553 patients receiving chronic opioid therapy for at least three months, and who experience OIC accompanied by chronic non-cancer pain.