BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Shionogi's constipation drug phase III study shows significant improvement

22 February 2016 | News | By BioSpectrum Bureau

Shionogi's constipation drug phase III study shows significant improvement

The US subsidiary of Osaka-based Shionogi has announced results of its pivotal phase III study (COMPOSE I). The study revealed that its once-daily treatment with naldemedine significantly improved opioid-induced constipation (OIC) compared to placebo in patients with chronic non-cancer pain.

The data, presented at the American Academy of Pain Medicine (AAPM) 2016 Annual Meeting in Palm Springs, CA, showed that naldemedine was generally well tolerated, with a low incidence rate of gastrointestinal (GI) related side effects.

Naldemedine is an investigational, oral, peripherally acting mu-opioid receptor antagonist (PAMORA) being studied for the treatment of OIC. The study found that for the primary endpoint 47.6 percent of patients taking an oral, once-daily 0.2 mg tablet of naldemedine experienced an increase in the frequency of spontaneous bowel movements (SBMs) from baseline for at least nine out of 12 weeks (including three out of the last four weeks) compared with 34.6 percent of patients on placebo over 12 weeks. Additionally, naldemedine significantly improved all key secondary endpoints, which included a significant increase in complete SBMs (CSBMs) per week, as well as SBMs without straining per week, from baseline to the last two weeks of the study period, as compared to placebo. Abdominal pain and diarrhea were the only treatment related adverse events that were reported in five percent or more of patients, with abdominal pain reported in 6.3 percent of patients on naldemedine vs. 1.8 percent on placebo, and diarrhea reported in 6.6 percent of patients on naldemedine vs. 2.9 percent on placebo.

"The millions of patients on chronic opioid therapy often suffer from constipation, which can be extremely debilitating and may lead to non-adherence and improper use of pain medications," said Juan Camilo Arjona Ferreira, MD, Senior Vice President Clinical Development. "We are very encouraged by the naldemedine study results, both in terms of its effect in treating OIC and its safety profile. We look forward to potentially delivering a new therapeutic solution to patients suffering from OIC."