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Astellas announces approval of Linzess Tablets in Japan

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Astellas Pharma and Ironwood Pharmaceuticals, recently announced that approval has been obtained in Japan for the guanylate cyclase-C receptor agonist “Linzess Tablets 0.25 mg (generic name: linaclotide)” for the additional indication of chronic constipation (other than constipation associated with organic disorders1) (“chronic constipation”).

Linzess Tablets 0.25 mg were licensed from Ironwood and have been developed and commercialized in Japan by Astellas. It was approved in Japan in December 2016 for the indication of irritable bowel syndrome with constipation (IBS-C)[2], and has been on the Japanese market since March 2017.

This approval is based on the results of a Phase 3, double-blind, placebo-controlled, parallel group trial conducted to evaluate the efficacy and safety of linaclotide orally administered for 4 weeks in 186 Japanese patients with chronic constipation. The subjects were randomly assigned to either the linaclotide (0.5 mg) or placebo group in a 1:1 ratio. In the linaclotide group, the change in weekly mean frequency of spontaneous bowel movement (SBM) at 1 week after the start of administration, which was the primary endpoint, represented a statistically significant improvement as compared to the placebo group. The most common adverse event was diarrhea, and its severity was mild to moderate in all cases.

Constipation is defined as the state in which feces cannot be excreted adequately and comfortably, and it is classified as chronic or transient condition depending on its duration. The prevalence of constipation in Japan has been reported as 2.5%

for men and 4.6% for women.

By providing a new therapy option with the additional chronic constipation indication, Astellas and Ironwood hope to be able to make a significant contribution to a large number of patients suffering from chronic constipation.

The impact of the approval of the additional chronic constipation indication has already been factored into Astellas' consolidated financial forecast for the fiscal year ending March 2019.