

Press Release

Astellas Submits Supplemental New Drug Application for Approval of Additional Indication of “Linaclotide” for Patients with Chronic Constipation in Japan

Tokyo, September 11, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced that it has submitted a supplemental new drug application for marketing approval of the guanylate cyclase-C receptor agonist “linaclotide (generic name) (brand name: Linzess[®] Tablets 0.25 mg)” for the additional indication of chronic constipation (other than constipation associated with organic disorders*1) (“chronic constipation”).

Linaclotide is a guanylate cyclase-C receptor agonist that was introduced from Ironwood Pharmaceuticals, Inc. (“Ironwood”) and has been developed and commercialized by Astellas in Japan. It was approved with the brand name of Linzess[®] Tablets 0.25 mg in Japan in December 2016 for the indication of irritable bowel syndrome with constipation (IBS-C)*2 and has been in the Japanese market since March 2017.

This application for 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. In this trial, the subjects were randomly assigned to either the linaclotide (0.5 mg) or the placebo group in a 1:1 ratio. The change in the weekly mean value for the frequency of spontaneous bowel movement (SBM)*3 at 1 week after administration, which was the primary endpoint, showed a statistically significant improvement in the linaclotide group as compared with the placebo group. The major adverse event was diarrhea, and its severity was mild to moderate in all cases.

Astellas expects to contribute to patients suffering from chronic constipation, by providing linaclotide as a new therapeutic option.

The submission of this application for an approval has no impact on the consolidated financial results of the fiscal year 2017 ending March 2018.

About linaclotide

Linaclotide locally binds to and activates guanylate cyclase-C receptors expressed on the epithelial cells in the intestinal mucosa, thereby facilitating intestinal secretion and transport and also improving visceral hyperalgesia. It has been approved in more than 30 countries worldwide for adults in the indications of

IBS-C and/or chronic idiopathic constipation. Astellas has the exclusive rights to develop and commercialize it in Japan based on the license agreement with Ironwood in 2009.

*1 Organic disorders: Disorders caused by the anatomical/pathological changes or abnormalities in the visceral, organic, nervous, or other tissues (detectable by examinations such as radiography and endoscopy).

*2 Irritable bowel syndrome constipation (IBS-C): A condition associated with irritable bowel syndrome (IBS) in which hard stools or “goat feces” constitute 25% or more and soft (mushy) or watery stools constitute less than 25% of feces. IBS is a functional disorder characterized by the absence of organic disorders and by its main gastrointestinal manifestations of abdominal pain/discomfort and abnormal bowel movement (diarrhea, constipation) that persist for a long time or relapse over time. The abnormal bowel movement and the abdominal symptoms associated with IBS are induced by various factors, including stress, that excessively activate the enteric nerves and eventually cause gastrointestinal hypermotility.

*3 Spontaneous bowel movement (SBM): A bowel movement occurring without treatments (the use of a laxative, suppository, or enema, disimpaction, etc.) on the same or the previous day.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management’s current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas’ intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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