Press Release

Marketing Approval of LINZESS®, Treatment for Irritable Bowel Syndrome with Constipation in Japan

- Provides a new therapeutic option for adult patients suffering from irritable bowel syndrome with constipation (IBS-C) –

Tokyo, December 19, 2016 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced that it obtained a marketing approval for a guanylate cyclase-C (GC-C) receptor agonist, LINZESS® (generic name: linaclotide Development Code: ASP0456) for irritable bowel syndrome with constipation[1)] (IBS-C) in adults by the Ministry of Health, Labour and Welfare in Japan today.

Astellas expects that obtaining marketing approval of LINZESS® will help patients who are suffering from IBS-C by providing a new therapeutic option.

The approval was obtained based mainly on the results from the double-blind, placebo-controlled, parallel-group comparative study in Phase III conducted in Japan in adults with IBS-C. This study randomized 500 adults with IBS-C in Japan. Patients were randomized 1:1 to receive either 500 mcg of LINZESS® or placebo for 12 weeks to examine clinical efficacy and safety of LINZESS®. The data indicates that patients treated with LINZESS® showed statistically significant improvement compared to placebo-treated patients for both co-primary endpoints. Regarding the first primary endpoint, 34% of patients treated with LINZESS® were Global Assessment of Relief of IBS Symptoms Responders, compared to 18% of placebo-treated patients ($p<0.001$). Regarding the second primary endpoint, 35% of patients treated with LINZESS® were Complete Spontaneous Bowel Movement (CSBM) Overall Responders, compared to 19% of placebo-treated patients ($p<0.001$). Additionally, improvements were achieved in pre-specified secondary endpoints in this trial covering abdominal and constipation symptoms, including bloating and abdominal pain/discomfort. Diarrhea rates in this trial were 9.6% for LINZESS® vs. 0.4% for placebo; all cases of diarrhea were characterized as mild or moderate in severity.

Upon this approval in Japan, Astellas will make the milestone payment of US $15 million to Ironwood, which has immaterial impact on Astellas' consolidated full-year business forecasts for the fiscal year ending March 31, 2017.

Product overview

Date of Approval: December 19, 2016

Brand Name: LINZESS®

Generic Name: linaclotide

Dosage Form/Content: Tablet containing 0.25 mg of linaclotide

Indication: Irritable bowel syndrome with constipation

Precautions with related to indication:

Application of this drug should be considered for adult patients whose symptom has not improved after dietary guidance and lifestyle guidance as the basics of the treatment for Irritable bowel syndrome with constipation are provided.

Dosage and Administration:

The usual adult dosage is 0.5 mg as linaclotide taken orally once daily before eating.

The dosage may be reduced to 0.25 mg depending on the symptoms.

Precautions with related to dosage and administration:

Since occurrence of severe diarrhea is possible, investigators are instructed to evaluate patients' symptoms periodically so that continuous administration of this drug will not be done unthinkingly.

About LINZESS®

LINZESS® is a GC-C receptor agonist. LINZESS® locally binds to the GC-C receptor expressed on the intestinal epithelium. Activation of the GC-C receptor results in improved visceral hypersensitivity, increased intestinal fluid secretion and accelerated intestinal transit. LINZESS® is approved for treatment of adults with IBS-C or chronic idiopathic constipation (CIC) and available in more than 30 countries. It is estimated that 2.9% of adults in Japan suffer from IBS-C [2)], and, until today, there were no prescription products currently approved in Japan for the treatment of this indication. Astellas entered into a license agreement with Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD, CEO: Peter Hecht, Ph.D., "Ironwood") in 2009 and Ironwood granted Astellas exclusive rights to develop and commercialize LINZESS® Tablets in Japan.

[1)] Irritable bowel syndrome (IBS) is a functional but not organic disorder which causes abdominal pain and/or discomfort with abnormal defecation including diarrhea and constipation. These gastrointestinal symptoms persist for a long period with frequent remissions and exacerbations. Abdominal pain/discomfort and abnormal defecation are often associated with various factors such as stress, which is considered to cause hypersensitivity of the enteric nervous system.

[2)] Kubo M, Fujiwara Y, Shiba M, Kohata Y, Yamagami H, Tanigawa T, et al. Differences between risk factors among irritable bowel syndrome subtypes in Japanese adults. Neurogastroenterol Motil. 2011;23:249-54.

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 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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