Press Release

Launch of LINZESS® Tablets 0.25mg in Japan

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

Tokyo, March 22, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced that it launched a guanylate cyclase-C (GC-C) receptor agonist, LINZESS® Tablets (generic name: linaclotide, "LINZESS®") for irritable bowel syndrome with constipation[1)] ("IBS-C") in Japan today.

IBS-C is a functional but not organic disorder which is characterized by abdominal pain and/or discomfort along with abnormal defecation. These gastrointestinal symptoms persist for a long period with frequent remissions and exacerbations.

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. It is estimated that 2.9% of adults in Japan suffer from IBS-C [1)], and, until today, there were no prescription products available 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.) in 2009 and was granted exclusive rights to develop and commercialize linaclotide in Japan. Astellas obtained marketing approval for LINZESS® in Japan in December 2016 for patients with IBS-C.

Astellas expects that the launch of LINZESS® will help patients in Japan who are suffering from IBS-C by providing a new therapeutic option.

1) 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.

Product overview

Brand Name: LINZESS® Tablet 0.25 mg

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 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

The safety and efficacy of the agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for uses being investigated. 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.

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.

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