

Astellas Pharma: Launches Irribow[®] OD Tablets in Japan for Diarrhea-predominant Irritable Bowel Syndrome

Tokyo, January 15, 2014 - [Astellas Pharma Inc.](#) (“Astellas Pharma”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced that the orally disintegrating tablet “Irribow[®] OD¹⁾ Tablets 2.5µg / 5µg” (generic name: ramosetron hydrochloride) become available in Japanese market today. They were approved for an additional formulation of Irribow[®] Tablet with the indication of diarrhea-predominant irritable bowel syndrome²⁾ (“IBS-D”) in male.

Irribow[®] OD Tablet is a drug for treating IBS-D developed using WOWTAB³⁾ which is one of the Astellas' proprietary drug delivery technologies. It can be ingested without water since it quickly disintegrates upon contact with saliva in the mouth. It can be easily taken even by elderly patients and patients with impaired swallowing function. It is also useful for patients with avoided water consumption and meets various needs of patients. Astellas offers Gaster[®] D Tablet for the treatment for peptic ulcers and gastritis, Harnal[®] D Tablet for the treatment for functional symptoms of benign prostatic hyperplasia and Vesicare[®] OD Tablet for overactive bladder, which were developed with using WOWTAB technology.

Irribow[®] Tablet is a serotonin 5-HT₃ receptor antagonist discovered by Astellas. Serotonin is a member of neurotransmitter which is greatly related to gastrointestinal motility, secretion and sensation. Stress may stimulate the serotonin release and activate the 5-HT₃ receptors on enteric nerve, which induces the acceleration of intestinal transit resulting in diarrhea. In addition, the increase in intracolonic pressure also induces serotonin release, and it will bind to 5-HT₃ receptor at the terminal of afferent neuron, causing intestinal nociceptive transmission to central nervous system.

Irribow[®] Tablet improves abnormal defecation associated with the acceleration of intestinal transit by inhibiting 5-HT₃ receptor selectively. It also improves visceral hypersensitivity by suppressing the transmission of intestinal nociception.

Astellas expects to further contribute to irritable bowel syndrome treatment by introducing Irribow[®] OD Tablet which can further improve the compliance with its more convenient dosing option.

Upon the launch of Irribow[®] OD Tablet, Astellas doesn't revise its current fiscal year (from April 1, 2013 to March 31, 2014) financial forecasts.

1) OD = Orally Disintegrating

2) 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 many factors such as stress, which is considered to cause the acceleration of intestinal transit resulted from the over-activation of enteric nervous system.

3) WOWTAB = **W**ithout **W**ater **T**ablet

Product outlines are as follows:

Brand name: Irribow[®] OD Tablets 2.5 μ g / Irribow[®] OD Tablets 5 μ g

Generic name: Ramosetron Hydrochloride

Indication: Diarrhea-predominant irritable bowel syndrome in males

Dosage regimen: The recommended oral dose for adult males is 5 μ g of ramosetron hydrochloride, once daily. The dosage can be increased or decreased depending on the patient's symptoms with a maximum dosage of 10 μ g a day.

Package: Irribow[®] OD Tablets 2.5 μ g: 100 Tablets (10 tablets x 10 sheets)

Irribow[®] OD Tablets 5 μ g: 100 Tablets (10 tablets x 10 sheets)

Drug Price: Irribow[®] OD Tablets 2.5 μ g: 85.80 Yen

Irribow[®] OD Tablets 5 μ g: 140.20 Yen

Date of NHI Price Listing: December 13, 2013

Date of Launch: January 15, 2014



With the objective of prevention of medical accidents, Astellas has adopted the user-friendly artwork on blisters, which make it easy to identify even when PTP sheet is divided, and worked on the improvements of medicine identification with (i) print of product name and dosage on each pocket (each medicine), (ii) ingenuity of letter size and color, (iii) display of efficacy and so on. The color and design of Irribow[®] OD Tablet are easy to identify for persons with impaired color vision.

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For inquiries or additional information

Astellas Pharma Inc.

Corporate Communications

TEL: +81-3-3244-3201, FAX:+81-3-5201-7473

<http://www.astellas.com/en>