

Astellas Pharma: Approval of Irribow® OD Tablets in Japan for Diarrhea-predominant Irritable Bowel Syndrome

Tokyo, August 15, 2013 - [Astellas Pharma Inc.](#) ("Astellas Pharma"; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced that it has obtained the marketing approval of Irribow[®] OD¹⁾ Tablets 2.5µg / 5µg (generic name: ramosetron hydrochloride) in Japan. They were approved for an additional formulation of Irribow[®] Tablets 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 into Japanese market Irribow[®] OD Tablet which can further improve the compliance with its more convenient dosing option.

Details of approval are as follows:

Brand name: Irribow® OD Tablets 2.5µg / Irribow® OD Tablets 5µg

Generic name: Ramosetron Hydrochloride

Indication: Diarrhea-predominant irritable bowel syndrome in males

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

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 = Without Water Tablet

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