

Astellas Pharma: Application for Orally Disintegrating Tablet YM060, a Treatment for Diarrhea-predominant Irritable Bowel Syndrome, in Japan

Tokyo, August 8, 2012 - [Astellas Pharma Inc.](#) (“Astellas Pharma”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) today announced that it submitted an application for market authorization for “orally disintegrating tablet YM060 (generic name: ramosetron hydrochloride)” to the Ministry of Health, Labour and Welfare in Japan. It has submitted for approval for an additional formulation of Irribow with the indication of the diarrhea-predominant irritable bowel syndrome¹⁾ in male.

“Orally disintegrating tablet YM060” is the irritable bowel syndrome treatment developed using WOWTAB²⁾ 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 for the treatment for peptic ulcers and gastritis, Harnal[®]D for the treatment for functional symptoms of benign prostatic hyperplasia and Vesicare[®]OD³⁾ for overactive bladder, which were developed with using WOWTAB technology.

Irribow 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 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 “orally disintegrating tablet YM060” which can further improve the compliance with its more convenient dosing option.

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

2) WOWTAB=Without Water Tablet

3) OD=Orally Disintegrating

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