

Astellas Submits Supplemental New Drug Application for Irribow[®]/Irribow[®] OD, a Treatment for Diarrhea-predominant Irritable Bowel Syndrome, in Japan

Tokyo, July 14, 2014 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) today announced that it submitted a supplemental new drug application for the indication of the diarrhea-predominant irritable bowel syndrome ¹⁾ in female for “Irribow[®] Tablets 2.5µg / 5µg and Irribow[®] OD ²⁾ Tablets 2.5µg / 5µg (generic name: ramosetron hydrochloride)” to the Ministry of Health, Labour and Welfare in Japan.

In October 2008, Astellas launched Irribow[®] Tablet with the indication of diarrhea-predominant irritable bowel syndrome in male in Japan, and launched the orally disintegrating tablet Irribow[®] OD Tablets for the same indication in January 2014. Astellas expects to contribute the treatment of females with the diarrhea-predominant irritable bowel syndrome by submission of this supplemental new drug application.

Irribow[®] Tablet / Irribow[®] OD Tablet are the serotonin 5-HT₃ receptor antagonist discovered by Astellas. Serotonin is a neurotransmitter which plays a key role in gastrointestinal motility, intestinal water secretion and sensation. Stress stimulates the serotonin release and activates 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 stimulates the serotonin release and activates the 5-HT₃ receptors on the terminal of afferent neuron, inducing intestinal nociceptive transmission to the central nervous system.

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

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 the acceleration of intestinal transit resulted from the over-activation of enteric nervous system.

²⁾ OD = Orally Disintegrating

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