

July 17, 2008

## **Astellas Receives a Japanese Marketing Approval for Irribow<sup>®</sup>**

Japan, July 17, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, "Astellas") today announced that it has received a Japanese marketing approval for Irribow<sup>®</sup> Tablets 2.5µg, 5µg (generic name: ramosetron hydrochloride) for the diarrhea-predominant irritable bowel syndrome in male. A New Drug Application had been submitted in January 2006.

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.

Irribow is a serotonin 5-HT<sub>3</sub> 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-HT<sub>3</sub> 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-HT<sub>3</sub> 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-HT<sub>3</sub> receptor selectively. It also improves visceral hypersensitivity by suppressing the transmission of intestinal nociception.

Astellas expects Irribow to provide a new option for IBS medication.

The launch timing will be announced after it appears in the NHI Drug Price List.

Details of approval are as follows:

Date of marketing approval: July 16, 2008  
Brand name: Irribow<sup>®</sup> Tablets 2.5µg, 5µg  
Generic name: ramosetron hydrochloride  
Indication: diarrhea-predominant irritable bowel syndrome in male  
Approval holder: Astellas Pharma Inc.

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