

October 6, 2008

## **Astellas Launches Irribow<sup>®</sup> for the Treatment of Irritable Bowel Syndrome**

Japan, October 6, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, “Astellas”) today announced that its serotonin 5-HT<sub>3</sub> receptor antagonist Irribow<sup>®</sup> Tablets 2.5μg, 5μg (generic name: ramosetron hydrochloride) will become available in Japan on October 7, 2008, with the indication of “diarrhea-predominant irritable bowel syndrome in male.”

Irritable bowel syndrome (IBS) is a functional but not organic disorder which causes abdominal pain and/or discomfort with abnormal bowel movement including diarrhea and constipation. These gastrointestinal symptoms persist for a long period with frequent remissions and exacerbations. Abdominal pain/discomfort and abnormal bowel movement 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. IBS is classified into three types consisted of diarrhea, constipation and both alternating between diarrhea and constipation. In Japan, it is reported that prevalence rate of all type of IBS in adult is expected to be 12.5% and the number of patients is estimated to be approximately 12 million. IBS is more likely to be observed in younger people, and the symptoms in male tend to develop diarrheal type.

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 bowel movement 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.

Details of Irribow are as follows:

Brand name: Irribow<sup>®</sup> Tablets 2.5µg, 5µg

Generic name: ramosetron hydrochloride

Indication: diarrhea-predominant irritable bowel syndrome in male

Dosage and administration: For oral use, the usual adult male dosage is 5 µg of ramosetron hydrochloride once daily. The dosage may be adjusted according to the patient's symptoms. The maximum daily dose is 10 µg.

Approval holder: Astellas Pharma Inc.

Packaging:

Tablets 2.5µg: 100 tablets (10T×10 PTP), 140 tablets (14T×10, PTP), 500 tablets (bottle),  
700tablets (14T×50 PTP)

Tablets 5µg: 100 tablets (10T×10 PTP), 140 tablets (14T×10, PTP), 500 tablets (bottle),  
700tablets (14T×50 PTP)

NHI reimbursement prices 86.30 Japanese yen/2.5µg tablet  
141.10 Japanese yen/5µg tablet

Date of NHI price listed : September 12, 2008

Date of launch: October 7, 2008

\*100 tablets (10T×10 PTP) and 500 tablets (bottle) will be available around December.

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