

### **Astellas Receives Approval for a Supplemental New Drug Application for Irribow<sup>®</sup>/Irribow<sup>®</sup> OD, a Treatment of Diarrhea-predominant Irritable Bowel Syndrome, in Japan**

Tokyo, May 26, 2015 - Astellas Pharma Inc. (“Astellas”; Tokyo: 4503; President and CEO: Yoshihiko Hatanaka) today announced that it received approval for a supplemental new drug application for the indication of the diarrhea-predominant irritable bowel syndrome<sup>1)</sup> in female patients for “Irribow<sup>®</sup> Tablets 2.5µg / 5µg and Irribow<sup>®</sup> OD<sup>2)</sup> Tablets 2.5µg / 5µg (generic name: ramosetron hydrochloride)” from the Ministry of Health, Labour and Welfare in Japan.

In October 2008, Astellas launched Irribow<sup>®</sup> Tablets with the indication of diarrhea-predominant irritable bowel syndrome in male patients in Japan, and launched the orally disintegrating tablet Irribow<sup>®</sup> OD Tablets for the same indication in January 2014. With this approval, Irribow<sup>®</sup>/Irribow<sup>®</sup> OD tablets are indicated for the treatment of diarrhea-predominant irritable bowel syndrome, allowing the use of both products for female patients suffering from this disease.

Irribow<sup>®</sup> Tablets / Irribow<sup>®</sup> OD Tablets are a serotonin 5-HT<sub>3</sub> receptor antagonist discovered by Astellas. Serotonin is a neurotransmitter which plays a key role in gastrointestinal motility, intestinal water secretion and sensation. Stress stimulates serotonin release and activates 5-HT<sub>3</sub> receptors on the enteric nerves, which accelerates intestinal transit, resulting in diarrhea. In addition, an increase in intracolonic pressure also stimulates serotonin release and activates 5-HT<sub>3</sub> receptors on abdominal visceral afferent nerve endings that signal pain to the central nervous system. Irribow<sup>®</sup> Tablets / Irribow<sup>®</sup> OD Tablets improve abnormal defecation associated with the acceleration of intestinal transit by selectively inhibiting 5-HT<sub>3</sub> receptors. The drug also improves abdominal pain and visceral hypersensitivity by inhibiting visceral nociceptive pain signaling.

Astellas expects that the additional indication for Irribow<sup>®</sup> Tablets / Irribow<sup>®</sup> OD Tablets will provide a new treatment option for female patients suffering from irritable bowel syndrome.

<sup>1)</sup> 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.

<sup>2)</sup> OD = Orally Disintegrating

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For inquiries or additional information

Astellas Pharma Inc.

Corporate Communications

TEL: +81-3-3244-3201, FAX:+81-3-5201-7473

<http://www.astellas.com/en>