

July 1, 2011

## **Astellas Pharma Inc.: Approval for Betanis<sup>®</sup> tablet, a Treatment for OAB, in Japan**

Tokyo, Japan, July 1, 2011 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Yoshihiko Hatanaka) today announced that Betanis<sup>®</sup> tablet (generic name: mirabegron) was granted a Japanese marketing approval for the indication of urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder (OAB\*) on July 1, 2011.

Betanis tablet is a once daily oral selective  $\beta_3$ -adrenoceptor agonist discovered and developed by Astellas. Betanis tablet enhances the urine collection function by activating  $\beta_3$ -adrenoceptor selectively on the bladder’s smooth muscles and relaxing bladder, and improves symptoms associated with OAB such as urgency, urinary frequency, and urge urinary incontinence. The Phase 3 study in Japan met its objective by demonstrating efficacy in mirabegron treatment groups in mean change from baseline in number of micturitions per 24-hour (primary endpoint) compared to placebo.

Astellas is developing mirabegron as a global project. The results of the Phase 3 studies in the U.S. and Europe were in line with those of the Japanese Phase 3 study and appear sufficient for regulatory submission. Astellas expects the submissions to FDA and EMA, respectively in 2Q fiscal year 2011. In Asia there is an ongoing multiregional Phase 3 study in China, Korea, Taiwan, and India.

Since the launch of Vesicare<sup>®</sup> in Japan with the first OAB indication in 2006, Astellas has contributed to improving the quality of life for patients suffering from OAB associated symptoms. Astellas expects to provide an additional option to the current standard therapy with anti-muscarinics including Vesicare, and further contribute to OAB treatment by introducing the world’s first oral selective  $\beta_3$ -adrenoceptor agonist with a different mechanism of action from anti-muscarinics.

\*OAB is associated with symptoms, such as, urinary frequency, urgency, nocturia and urge incontinence. According to the Japanese Neurogenic Bladder Society, the number of OAB patients in Japan is equivalent to nearly 12 percent of men and women aged 40 years or older. These symptoms can cause significant inconvenience and mental distress in a patient’s daily life.

PRODUCT SUMMARY

Product name: Betanis<sup>®</sup> tablet 25mg/50mg

Generic name: mirabegron

Indication: Urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder

Dosage regimen For oral use, the usual adult dosage is 50 mg of mirabegron once daily after meal

Betanis has a warning in its label to refrain from using in patients of reproductive age wherever possible based upon findings in animal studies (rat).

###

Contacts for inquiries or additional information
Astellas Pharma Inc. Corporate Communications Tel: +81-3-3244-3201 Fax: +81-3-5201-7473 <a href="http://www.astellas.com/en">http://www.astellas.com/en</a>