

September 15, 2011

Astellas Pharma Inc. Launches Betanis[®] Tablet, a Treatment for OAB, in Japan

-Provides a New Option for Patients with OAB -

Tokyo, Japan, September 15, 2011 - [Astellas Pharma Inc.](#) (Tokyo:4503, "Astellas") today announced that Betanis[®] tablet 25mg/50mg (generic name: mirabegron) will become available in the Japanese market on 16 September, 2011, for the indication of urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder (OAB).

Betanis tablet is a once daily oral selective β_3 -adrenoceptor agonist discovered and developed by Astellas. Betanis tablet enhances the urine collection function by activating β_3 -adrenoceptors selectively on the bladder's smooth muscles and relaxing the bladder, and thus 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 hopes to offer mirabegron throughout the world and submitted a New Drug Application and a Market Authorisation Application for mirabegron to the European Medicines Agency and the U.S. Food and Drug Administration, respectively, in August, 2011. In Asia there is an ongoing multiregional Phase 3 study in China, Korea, Taiwan, and India.

Since the launch of Vesicare[®] in Europe (2004), the US (2005) and Japan (2006), Astellas has contributed to improving the quality of life for patients suffering from OAB associated symptoms across the world. Astellas expects to provide a new 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 β_3 -adrenoceptor agonist with a different mechanism of action from anti-muscarinics. Astellas anticipates that peak sales of Betanis may reach 11.1 billion yen (based on NHI drug price) in FY2020.

PRODUCT SUMMARY

Product name:	Betanis [®] 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 a meal
Package:	Betanis [®] tablet 25mg: 100 Tablets Betanis [®] tablet 50mg: 100 Tablets
Drug Price:	Betanis [®] tablet 25mg: 113.00Yen Betanis [®] tablet 50mg: 189.80Yen
Drug price listing date:	12 September, 2011
Sales commencement date:	16 September, 2011 (Plan)

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

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