

August 29, 2011

Astellas Pharma Inc.: Announcement of Regulatory Submission for Mirabegron (YM178), a Treatment for Overactive Bladder, in U.S. and Europe

Tokyo, August 29, 2011 - [Astellas Pharma Inc.](#) (Tokyo:4503, "Astellas") today announced the submission of a New Drug Application and Market Authorisation Application for mirabegron (generic name / code name: YM178) to the U.S. Food and Drug Administration and the European Medicines Agency. The submissions were sent on August 24 and 26, 2011 (Europe and US, respectively). Astellas is seeking approval for this first in a new class of medicine for the indication of overactive bladder (OAB*) associated with symptoms of urgency, urinary frequency, and urge urinary incontinence.

Mirabegron is a once daily oral selective β_3 -adrenoceptor agonist discovered and developed by Astellas. The pivotal Phase 3 clinical trials in the U.S. and Europe met primary endpoints compared to placebo.

Astellas has been developing mirabegron as a global project. In Japan, Astellas was granted marketing approval under the trade name of Betanis[®] tablet in July 2011. Additionally, there is an on-going multiregional Phase 3 study in China, Korea, Taiwan, and India.

Astellas markets the OAB medication solifenacin succinate (known as VESiCare) in **67 countries/areas and has contributed to improving OAB associated symptoms.

**OAB is associated with symptoms such as urinary frequency, urgency, nocturia and urge incontinence. In the U.S. and Europe, >12% of adults and 30-40% of adults 75 years of age and over are estimated to have some sort of OAB symptoms (Wein AJ, Rovner ES. The overactive bladder: an overview for primary care health providers. Int J Fertil Womens Med. 1999;44:56-66).*

*** as of July 2011*

About VESiCare

INDICATION AND DOSAGE

VESiCare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. The recommended dose of VESiCare is 5 mg once daily. If the 5-mg dose is well tolerated, the dose may be increased to 10 mg once daily.

IMPORTANT SAFETY INFORMATION

VESiCare is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients with hypersensitivity to the product.

Angioedema of the face, lips, tongue and/or larynx have been reported with VESiCare. In some cases angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life

threatening. If involvement of the tongue, hypopharynx, or larynx occurs, VESicare should be promptly discontinued and appropriate therapy and/or measures necessary to ensure a patent airway should be promptly provided.

VESicare should be administered with caution to patients with bladder outflow obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or reduced renal or hepatic function. Doses of VESicare higher than 5 mg are not recommended in patients with severe renal impairment, moderate hepatic impairment, or when administered with ketoconazole or other potent CYP3A4 inhibitors. Use of VESicare in patients with severe hepatic impairment is not recommended.

In placebo-controlled studies, the most common adverse events reported by patients were dry mouth (10.9%, 27.6%, 4.2%), constipation (5.4%, 13.4%, 2.9%), blurred vision (3.8%, 4.8%, 1.8%), and dyspepsia (1.4%, 3.9%, 1.0%) with VESicare 5 mg, 10 mg, and placebo, respectively.

The overall rate of serious adverse events was 2%. For the 10-mg dose, three intestinal serious adverse events were reported (one fecal impaction, one colonic obstruction, and one intestinal obstruction). For the 5-mg dose, one case of angioneurotic edema was reported.

For more information please visit our website at: <http://www.astellas.us/docs/vesicare.pdf>

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