

December 22, 2009

Application for Orally Disintegrating Tablet YM905 in Japan

Japan, December 22, 2009 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced that it submitted an application for market authorization for “orally disintegrating tablet YM905 (generic name: solifenacin succinate) “ to the Pharmaceuticals and Medical Devices Agency (PMDA) on December 22, 2009 in Japan. It has submitted for approval for an additional formulation of the overactive bladder treatment Vesicare[®] with the indication of urinary frequency, urgency, and urge incontinence associated with overactive bladder (OAB*).

“Orally disintegrating tablet YM905” is the OAB treatment developed using WOWTAB** which is one of the Astellas' proprietary drug delivery technologies. It can be ingested without water since it quickly disintegrates upon contact with saliva in the mouth. It can be easily taken even by elderly patients and patients with impaired swallowing function. It is also useful for patients with avoided water consumption and meets various needs of patients. Astellas offers Gaster^{®D} for the treatment for peptic ulcers and gastritis and Harnal^{®D} for the treatment for functional symptoms of benign prostatic hyperplasia, which were developed with using WOWTAB technology.

Vesicare[®] is a muscarine receptor antagonist discovered and developed by Astellas and is the first drug approved for OAB in Japan. It relaxes bladder smooth muscles and improves symptoms associated with OAB such as urinary frequency, urgency and urge incontinence by blocking muscarine receptors on bladder smooth muscles. It was launched in 2006 in Japan and has been already marketed in more than 50 countries and areas.

Astellas expects to further contribute to OAB treatment by introducing into Japanese market “orally disintegrating tablet YM905” which can further improve the compliance with its more convenient dosing option.

*OAB is caused by excessive contraction of smooth muscles of the urinary bladder and is associated with symptoms such as mainly urinary frequency, urgency, nocturia and urge incontinence. According to Neurogenic Bladder Society, the number of OAB patients is estimated to be about 8.1 million, nearly 12% of men and women aged 40 years or older In Japan. These symptoms cause significant inconvenience and mental distress in patient’s activities of daily living.

**WOWTAB=Without Water Tablet

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