

June 18, 2010

Application for Mirabegron (YM178), a Treatment for OAB, in Japan

Tokyo, Japan, June 18, 2010 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced that it submitted a market authorization application for mirabegron (generic name / code name: YM178) to the Pharmaceuticals and Medical Devices Agency (PMDA) today in Japan. Astellas is seeking approval for the indication of urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder (OAB*).

Mirabegron is a once daily oral β_3 -adrenoceptor agonist discovered and developed by Astellas. Mirabegron enhances the urine collection function by activating β_3 -adrenoceptor on the bladder’s smooth muscles and the 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. Also, based on the safety results in Phase 3 study, mirabegron appears to be safe and well tolerated and the incidence of anti-cholinergics side effects, such as dry mouth, was low and comparable to those in the placebo group.

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. In Asia there is an ongoing multiregional Phase 3 study in China, Korea, Taiwan, and India.

Since the launch of Vesicare[®] 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 anti-cholinergics including Vesicare, and further contribute to OAB treatment by introducing into the Japanese market mirabegron with a different mechanism of action from anti-cholinergics.

*OAB is associated with symptoms, such as, urinary frequency, urgency, nocturia and urge incontinence. According to the Neurogenic Bladder Society, there is an estimated 8.1 million OAB patients in Japan, which 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.

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