News Release

Astellas Pharma Inc.: Receipt of Filing Communication Letter from U.S. FDA Regarding Mirabegron (YM178)

Tokyo, November 11, 2011 - Astellas Pharma Inc. (Tokyo: 4503, "Astellas") today announced the receipt of a letter from the U.S. Food and Drug Administration (FDA) indicating that it accepted for filing the New Drug Application for mirabegron (generic name / code name: YM178) and initiated a substantive review. The target date for the review completion (PDUFA date) is June 29, 2012.

A similar letter from the European Medicines Agency (EMA) validating the application and confirming the start of the review procedure was received.

The submissions were sent on August 24 and 26, 2011 (to the EMA and the FDA, 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.

For inquiries or additional information

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