For Immediate Release

FDA Advisory Committee Recommends Approval of Mirabegron – Investigational Overactive Bladder Treatment from Astellas

DEERFIELD, Ill., April 5, 2012 – Astellas Pharma US, Inc. ("Astellas"), a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), announced today that the Reproductive Health Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted that the overall risk/benefit assessment supports approval of mirabegron (YM178) for the treatment of overactive bladder (OAB) (Yes: 7, No: 4, Abstain: 1).

Today's committee recommendation, although not binding, will be considered by the FDA as it reviews the New Drug Application (NDA). The FDA is expected to issue an action letter on the mirabegron application by June 29, 2012.

Mirabegron is a once daily oral selective β3-adrenoceptor agonist discovered and developed by Astellas. Mirabegron has been studied extensively in more than 10,000 individuals over the last 10 years.

"We are pleased with the committee's recommendation, which marks an important step in bringing a new treatment option to the more than 42 million Americans living with overactive bladder," said Steven Ryder, MD, president, Astellas Pharma Global Development. "If approved, mirabegron will offer patients and physicians the first new oral mechanism of action in OAB treatment since the launch of the first anticholinergic agent 30 years ago. Mirabegron and other pipeline products are part of Astellas' commitment to advancing urological health."

Mirabegron uses a distinct mechanism of action versus antimuscarinics, the current treatment standard. Antimuscarinics work by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions. Mirabegron works by stimulating the β3 receptors in the detrusor muscle of the bladder, causing relaxation of the bladder muscle during the storage phase of the micturition (urination) cycle. This improves the storage capacity of the bladder without diminishing bladder contraction during bladder voiding.

Astellas submitted a New Drug Application for mirabegron to the FDA on Aug. 26, 2011. Regulatory applications for mirabegron are also under review in several other countries. In July 2011, mirabegron was granted marketing approval in Japan and was launched in September 2011.

About Overactive Bladder

According to the National Association for Continence, one in five adults has overactive bladder. However, recent studies have found that many more people may be affected, but have not talked to their physicians out of embarrassment or belief that OAB cannot be treated. For people with OAB, inappropriate signals are sent to the muscles in the bladder causing them to contract before the bladder is full. These bladder contractions may cause strong, sudden urges, and a

frequent need to go to the bathroom, sometimes without any advance warning. Many patients cope with their symptoms by restricting fluids, carrying extra clothing and “mapping” bathroom locations wherever they go.

About Astellas
Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.us.

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