

## PRESS RELEASE

### NEW CLASS OF TREATMENT NOW AVAILABLE FOR PATIENTS WITH OVERACTIVE BLADDER

**Chertsey, UK, 26 February 2013** – ASTELLAS PHARMA EUROPE Ltd. has today announced that BETMIGA™ (mirabegron) is now available in the UK for use as a once daily therapy for the symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB),<sup>1</sup> a condition that affects around 7 million adults in the UK.<sup>2</sup>

Mirabegron is the first in a new class of OAB treatment for over 30 years, offering healthcare professionals an alternative option to antimuscarinics, the standard treatment of care.<sup>3</sup>

A once daily oral  $\beta$ 3-adrenoceptor agonist, mirabegron has a distinct and novel mechanism of action compared to antimuscarinics.<sup>3</sup> Mirabegron works by stimulating the  $\beta$ 3 receptors in the detrusor muscle of the bladder<sup>4</sup> causing relaxation of the bladder muscle during the storage phase of the micturition cycle. This improves the storage capacity of the bladder without inhibiting bladder voiding,<sup>5</sup> whereas antimuscarinics work by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions.

The availability of a new class of OAB treatment is important because of low adherence with antimuscarinics. Around half of patients discontinue antimuscarinic treatment after only three months,<sup>6</sup> often due to lack of efficacy or intolerable side effects. In one study, 46% of patients discontinued their antimuscarinic treatment due to insufficient response and 21% of patients due to side effects.<sup>7</sup> The most common adverse reactions reported for patients treated with mirabegron 50mg during the three 12-week phase III double blind placebo controlled studies are tachycardia and urinary tract infections (1.2% and 2.9% respectively).<sup>1</sup> Serious adverse reactions included atrial fibrillation (0.2%).<sup>1</sup>

*“The introduction and availability of mirabegron in the treatment of OAB symptoms offers a new way of treating adult patients, providing an alternative treatment option without one of the most bothersome side effects of antimuscarinics. I would suggest clinicians consider new treatment options for their OAB patients moving forward, taking advantage of the new and innovative options available.”* commented Professor Chris Chapple, Consultant Urological Surgeon at Sheffield Teaching Hospitals and Lead Investigator of the mirabegron 12 month safety and tolerability study<sup>9</sup>.

Mirabegron has demonstrated clinically and statistically significant improvements in the comprehensive clinical trial evidence from 7 phase II / III studies in which over 5,000 patients received mirabegron, including three Phase III double-blind, randomised controlled trials conducted in the US and Europe-Australia.<sup>8,9,10</sup> In the trials, mirabegron demonstrated superior efficacy compared to placebo in the treatment of symptoms of OAB, with patients needing to visit a toilet significantly less frequently and experiencing fewer incontinence episodes.<sup>8,9,10</sup> In terms of quality of life, treatment of the symptoms of OAB with

mirabegron once daily has also demonstrated statistically significant improvements over placebo on quality of life measures such as treatment satisfaction and symptom bother.<sup>11</sup>

Mirabegron is now available via prescription in the UK, it will become available throughout Europe as part of a phased launch plan.

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**Notes to editors**

**About mirabegron:**

Mirabegron is a once daily oral  $\beta_3$ -adrenoceptor agonist discovered and developed by Astellas. It is the first compound licensed in this new class of treatment for OAB, using a distinct mechanism of action compared to antimuscarinics, the current treatment standard.<sup>3</sup> Antimuscarinics work by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions. Mirabegron works by stimulating the  $\beta_3$  receptors in the detrusor muscle of the bladder causing relaxation of the bladder muscle during the storage phase of the micturition cycle.<sup>4</sup> This improves the storage capacity of the bladder without impeding bladder voiding.<sup>5</sup>

**About overactive bladder:**

Overactive bladder (OAB) is characterised by symptoms of urinary urgency, with or without urgency incontinence, usually with increased daytime frequency and nocturia (awakening at night one or more times to empty the bladder).<sup>12</sup> OAB is a common condition, affecting around 7 million adults in the UK.<sup>2</sup> A survey of over 16,000 adult men and women in six European countries revealed that 17% of respondents had symptoms of OAB.<sup>13</sup> Prevalence of OAB increases with age, with 30% to 40% of those aged over 75 years affected.<sup>13</sup> OAB can also have a major impact on quality of life. In the survey, a majority (65%) of respondents indicated their daily lives were adversely affected.<sup>13</sup>

Astellas submitted a New Drug Application and Market Authorisation Application for mirabegron to the U.S. Food and Drug Administration and the European Medicines Agency in August 2011 and received FDA authorisation on 28th June 2012, and European authorisation from the European Commission on 21st December 2012. In Japan, Astellas was granted marketing authorisation under the trade name of BETANIS<sup>®</sup> tablet in July 2011. Additionally, there is a recently completed multiregional Phase III study in China, Korea, Taiwan and India.

For full details of adverse events, please consult the Summary of Product Characteristics (SmPC).

## About Astellas Pharma Europe Ltd.:

Astellas Pharma Europe Ltd., located in the UK, is the European headquarters of Tokyo-based Astellas Pharma Inc.

Astellas is one of the top 20 pharmaceutical companies in the world, employing 17,000 people globally. As a well-established and forward-thinking company, Astellas contributes towards improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has a solid and proven track record in Urology, making it a Global Category Leader (GCL) in this field of medicine, committed to improving the lives of patients with urological conditions.

Its current urology portfolio includes treatments for benign prostatic hyperplasia (BPH), overactive bladder (OAB) and prostate cancer. With a strong emphasis on research and development, Astellas is dedicated to finding new treatments to meet unmet medical needs and has a number of treatments for urological conditions in development. As part of its ongoing commitment to the field, Astellas Pharma Europe Ltd. also provides and supports a wide range of educational opportunities for those working in the field of urology, designed to progress professional expertise and improve patient outcomes.

## References:

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