PRESS RELEASE

For immediate release

MIRABEGRON RECEIVES POSITIVE CHMP OPINION FOR TREATMENT OF OVERACTIVE BLADDER SYMPTOMS

Chertsey, UK, 19th October 2012. ASTELLAS PHARMA EUROPE Ltd. announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending the granting of a marketing authorisation for BETMIGA™ (mirabegron) for the symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.

The opinion now needs ratification by decision of the European Commission which is expected within the next 74-90 days. If approved, mirabegron will be the first in a new class of OAB treatment, offering healthcare professionals an alternative option to antimuscarinics (currently the only licensed oral treatment option) when treating patients with OAB.

Mirabegron is a once daily oral β_3-adrenoceptor agonist with a distinct mechanism of action compared to antimuscarinics, the current treatment standard.[1] Antimuscarinics work by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions. Mirabegron works by stimulating the β_3 receptors in the detrusor muscle of the bladder[2] 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.[3]

The positive opinion was reached after the CHMP reviewed 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.[4,5,6] 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.[4,5,6] 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.[7]

Astellas Pharma Europe Ltd. is an established leader in urology in Europe, 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 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.

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Notes to editors

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).[8]

OAB is a common condition. A survey of over 16,000 adult men and women in six European countries revealed that 17% of respondents had symptoms of OAB.[9] Prevalence of OAB increases with age, with 30% to 40% of those aged over 75 years affected.[9] 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.[9]

About mirabegron

Mirabegron is a once daily oral β_3-adrenoceptor agonist discovered and developed by Astellas. It is the first compound submitted for regulatory approval in this new class of treatment for OAB, using a distinct mechanism of action compared to antimuscarinics, the current treatment standard.[1] Antimuscarinics work by binding to muscarinic receptors in the

bladder and inhibiting involuntary bladder contractions. Mirabegron works by stimulating the β_3 receptors in the detrusor muscle of the bladder causing relaxation of the bladder muscle during the storage phase of the micturition cycle.[2] This improves the storage capacity of the bladder without impeding bladder voiding.[3]

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 approval on 28th June 2012, and CHMP opinion today. In Japan, Astellas was granted marketing approval under the trade name of BETANIS® tablet in July 2011. Additionally, there is a recently completed multiregional Phase III study in China, Korea, Taiwan, and India.

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 a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative pharmaceuticals. The organisation's focus is to deliver outstanding R&D and marketing to continue growing in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 4,300 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

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