For immediate release

NEW CLASS OF TREATMENT FOR OVERACTIVE BLADDER APPROVED IN EUROPE

Astellas Pharma Europe Ltd., Chertsey, UK, 11th January 2013. A new treatment, BETMIGA™ (mirabegron) has received approval from the European Commission (EC) for the treatment of overactive bladder (OAB) symptoms in adults.[1] Mirabegron represents the first new class of treatment in OAB for over 30 years. Currently around half of patients discontinue OAB treatment after only three months, often due to lack of efficacy or side effects,[2,3] so it is important that doctors will now be able to offer patients an alternative treatment that works in a different way.

OAB affects more than 400 million people worldwide.[4] In Europe, OAB affects approximately 17% of men and women and increases to 30-40% for those aged over 75 years.[5] In a survey carried out in OAB patients, 65% felt OAB had adversely affected their daily life.[5] Symptoms can affect family, social and work life, as well as mental and physical wellbeing,[6] and across OAB patients, depression scores are higher, whilst quality of life scores are lower.[7]

Mirabegron will offer doctors an alternative to antimuscarinic agents, the only class of approved oral treatment previously available. Mirabegron has a completely different mechanism of action to antimuscarinics;[8] it improves the storage capacity of the bladder without inhibiting bladder voiding, thereby prolonging the time between trips to the toilet for the patient.[9] Dry mouth is one of the most common and bothersome side effects of antimuscarinics and often the reason for discontinuation of treatment. In comparison, studies have shown that mirabegron has a low incidence of treatment-associated side effects, including dry mouth.[8,10,11,12,13]

In terms of quality of life, research presented at the 2011 American Urological Association (AUA) annual congress demonstrated that patients with OAB who received mirabegron reported significant improvements in treatment satisfaction, symptom bother, disease perception and quality of life, in comparison with patients taking a placebo.[14]

“The introduction of mirabegron should lead to a shift in how we treat OAB symptoms in adults. It has been over 30 years since a new class of oral treatment was available for OAB patients so we are looking forward to being able to offer an effective medication without the more bothersome side effects associated with antimuscarinics,” commented Professor Chris Chapple, Consultant Urological Surgeon at Sheffield Teaching Hospitals and Lead Investigator of the mirabegron 12 month safety and tolerability study. “I see patients every

day who are struggling to cope with this chronic condition. OAB can have a significant impact on a patient's quality of life. The introduction of mirabegron offers existing patients and those newly diagnosed with OAB a real alternative to current treatments."

The European Commission granted approval of mirabegron following the recommendation by the Committee for the Medicinal Products for Human Use (CHMP) in October 2012. They reviewed extensive clinical trial evidence from 7 Phase II / III studies in which over 5,000 patients received mirabegron, including 3 Phase III double-blind, randomised controlled trials conducted in the US and Europe-Australia.[10,11,12] 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.[10,11,12] 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 of treatment satisfaction and symptom bother.[14]

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), 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

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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).[15]

About mirabegron:

Mirabegron is a once daily oral β_3-adrenoceptor agonist discovered and developed by Astellas. It is the first compound approved in this new class of treatment for OAB, using a novel mechanism of action compared to antimuscarinics, the current treatment standard.[7] 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 muscle of the bladder causing relaxation of the bladder muscle, improving the storage capacity of the bladder without impeding bladder voiding.[9]

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 European approval on 20th December 2012. 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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