

**ASTELLAS RECEIVES MARKETING AUTHORISATION FOR VESOMNI™ FROM THE  
NETHERLANDS MEDICINES EVALUATION BOARD**

**Netherlands first to approve new fixed-dose combination treatment for men with lower  
urinary tract symptoms associated with BPH**

**Chertsey, UK, 23 MAY 2013.** ASTELLAS PHARMA EUROPE B.V., the European subsidiary of Tokyo-based Astellas Pharma Inc.(Tokyo:4503), today announced the Dutch Medicines Evaluation Board (MEB) has granted marketing authorisation for VESOMNI in the Netherlands.

The market authorisation granted for VESOMNI is for “treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not adequately responding to treatment with monotherapy”.<sup>1</sup>

The Netherlands will be the Reference Member State for further registration of VESOMNI throughout Europe as part of future Mutual Recognition Procedures.

VESOMNI is a film-coated, bi-layered modified release tablet, for once-daily treatment. Each tablet contains 6 mg of the antimuscarinic solifenacin and 0.4 mg of the alpha<sub>1</sub>-adrenoceptor antagonist (α<sub>1</sub>-blocker) tamsulosin (in the oral controlled absorption system [OCAS™]) (TOCAS).

Phase III data demonstrated that VESOMNI offered statistically significant improvements vs. TOCAS on storage parameters and quality of life in men with moderate to severe storage symptoms and voiding symptoms aged 45 years and over.<sup>2</sup> In addition, VESOMNI demonstrated statistically significant improvements vs. placebo over all key endpoints.<sup>2</sup>

In the Phase III study, the most frequently occurring adverse events for VESOMNI were dry mouth and constipation, which were mostly mild in nature.<sup>2</sup>

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## **Notes to editors**

### **About LUTS / BPH**

Lower urinary tract symptoms (LUTS) associated with BPH are common in men and can include storage symptoms (frequency, urgency, nocturia) and/ or voiding (e.g. hesitancy, intermittency).<sup>3</sup> In a study of 14,139 men aged 40 years and over, 71% reported at least one LUTS.<sup>4</sup> 49% of the men with LUTS reported both storage and voiding symptoms.<sup>4</sup>  $\alpha$ -blockers are currently first-line treatment for voiding symptoms in men with LUTS/BPH but often do not adequately relieve storage symptoms.<sup>5</sup> Storage symptoms are the most bothersome to the patient<sup>4</sup> and can have a significant impact on quality of life.<sup>6</sup>

### **Astellas Pharma Europe B.V.**

Astellas' European hub for R&D is located in Leiden, Netherlands, along with the Company's Sales & Marketing office for The Netherlands, and the International affiliate which manages Sales & Marketing across the Middle East and Africa.

Astellas has had an established presence in The Netherlands since 1991, when Japanese company Yamanouchi acquired the pharmaceutical division of Royal Gist Brocades, the Dutch biotechnology company. This provided the foundation for the R&D centre in Leiden. On 1<sup>st</sup> April 2005 Yamanouchi merged with another Japanese pharmaceutical company, Fujisawa, to form Astellas, a global pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals.

Worldwide, Astellas employs approximately 17,000 people, more than 4,300 of whom are based in Europe, the CIS states and Africa. The 2005 merger has strengthened Astellas' position on the European market by enabling the company to operate in a larger geographical area within the continent, and the company now has independent locations in over 21 countries, one R&D site and three production facilities.

Astellas employs approximately 850 fulltime employees (FTEs) in The Netherlands, who work at two locations (Leiden and Meppel).

### **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](http://www.astellas.eu).

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