

PRESS RELEASE

ASTELLAS FILES REGULATORY SUBMISSION FOR EC905 – A NEW FIXED DOSE COMBINATION TREATMENT FOR MALE LUTS

Staines, 27th March 2012. ASTELLAS PHARMA EUROPE Ltd., the European subsidiary of Tokyo – based [Astellas Pharma Inc.](#) (Tokyo:4503) today announced the submission of a Market Authorisation Application for EC905 in the Netherlands. This application for approval is the first step of the European-wide mutual recognition process to authorise the drug in other EU countries. The submission was sent on 2nd March 2012.

EC905 is a combination tablet containing solifenacin 6 mg and tamsulosin OCAS 0.4 mg. Astellas is seeking approval for this new fixed dose combination therapy to treat lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia, with storage symptoms.

This announcement follows presentation of Phase III data on EC905 at the European Association of Urology annual congress in Paris on 26th February 2012. The data demonstrated that EC905 offered significant benefits over placebo, and was more effective than tamsulosin alone on storage parameters and quality of life in men with LUTS with voiding and storage symptoms aged 45 years and over.¹

LUTS are common in men and include symptoms of voiding (e.g. hesitancy, intermittency), storage (frequency, urgency, nocturia) and post-micturition (feeling of incomplete bladder emptying).² In a study of four European countries plus Canada, LUTS affected over 60% of the adult male population.³ Storage symptoms associated with LUTS are synonymous with overactive bladder syndrome, which can have a significant negative impact on quality of life, including work, social activities and sexual relationships.⁴

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 and reliable pharmaceuticals. The organisation is committed to becoming a global company by combining outstanding R&D and marketing capabilities and continuing to grow 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 4,200 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

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