

## **Astellas Receives European Marketing Authorisation for VIBATIV® for Nosocomial Pneumonia Caused by MRSA<sup>1</sup>**

**Staines, United Kingdom, September 15, 2011** – Astellas Pharma Europe Ltd., a subsidiary of Tokyo based Astellas Pharma Inc. announced today that the European Commission has granted marketing authorisation for VIBATIV® (telavancin hydrochloride),<sup>1</sup> following the Committee for Human Medicinal Products' (CHMP) positive opinion in May 2011. VIBATIV, discovered by Theravance, Inc., is a bactericidal, once-daily injectable lipoglycopeptide antibacterial agent with a dual mechanism of action against Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA).<sup>2</sup>

The VIBATIV marketing authorisation from the European Commission is granted for the treatment of adults with nosocomial pneumonia (hospital-acquired), including ventilator associated pneumonia, known or suspected to be caused by MRSA. VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable. Launch plans are under review by Astellas.

*"The approval of VIBATIV can provide European healthcare professionals with a new, effective hospital antibiotic option for patients with hospital-acquired pneumonia caused by MRSA,"* said Ken Jones, President and CEO of Astellas Pharma Europe.

VIBATIV was licensed from Theravance, Inc. for global commercialisation. VIBATIV was approved in the United States in September 2009, and in Canada in October 2009, for adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria.<sup>3</sup>

Patients with nosocomial pneumonia suspected or proven to be caused by Gram-positive bacteria were enrolled in the ATTAIN programme. This included ATTAIN I and ATTAIN II, two large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies, in which 1,503 patients were enrolled and treated either with VIBATIV 10 mg/kg IV once daily or vancomycin 1 g IV every 12hr (the protocols allowed vancomycin dosage to be modified per site-specific guidelines). For patients with suspected or proven polymicrobial infections involving Gram-negative and/or anaerobic bacteria in addition to the Gram-positive organisms for which study medication therapy was used, aztreonam and piperacillin-tazobactam were allowed. The objective of each study was non-inferiority of VIBATIV versus vancomycin in clinical cure rate at the test-of-cure visit. Determination of clinical cure was based upon physician-judged resolution of clinical signs and symptoms of nosocomial pneumonia. In both studies, VIBATIV achieved the objective of non-inferiority compared to vancomycin.<sup>4</sup>

Astellas has an ongoing commitment to combating infectious diseases through the worldwide launch of its injectable antifungal echinocandin, MYCAMINE™ (micafungin), which has been used to treat more than 750,000 patients worldwide. In addition, Astellas has entered into a global partnership with Basilea Pharmaceuticals Ltd. to co-develop and co-promote isavuconazole, an azole antifungal for the treatment of invasive fungal infections, including Aspergillosis, currently in Phase 3 trials; and with Optimer Pharmaceuticals Inc. to develop and commercialise fidaxomicin, an investigational antibiotic under regulatory review as a novel treatment for *Clostridium difficile* infection in Europe and certain other countries.

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**References:**

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3. VIBATIV US prescribing information May 2011. <http://www.vibativ.com/PrescribingInformation.aspx> Accessed August 2011
4. Rubenstein E, Lalani T, Corey GR, *et al.* Telavancin versus vancomycin for hospital-acquired pneumonia due to Gram positive pathogens. *Clin Infect Dis* 2011;52:31-40

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**About Astellas Pharma Inc.**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 16,000 employees worldwide. The organisation is committed to becoming a global category leader in Urology, Immunology including Transplantation and Infectious Diseases, Oncology, Neuroscience, DM Complications and Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company website at [www.astellas.com/en](http://www.astellas.com/en).

**About Astellas Pharma Europe Ltd.**

Astellas Pharma Europe Ltd., located in the UK, is a European subsidiary 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 4000 staff across these regions. For more information about Astellas Pharma Europe, please visit [www.astellas.eu](http://www.astellas.eu).