News Release

Astellas Receives Positive Opinion from CHMP for European Approval of VIBATIV™ for Nosocomial Pneumonia caused by MRSA

New Treatment Option for Adult Patients with Nosocomial Pneumonia, Including critically ill Patients with Ventilator Associated Pneumonia

Tokyo, Japan, May 23, 2011 - Astellas Pharma Inc. (Tokyo:4503, "Astellas") and its European subsidiary, Astellas Pharma Europe Ltd.("APEL") announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the granting of marketing authorisation for VIBATIV (telavancin hydrochloride) for the treatment for adults with nosocomial (hospital acquired) pneumonia, including ventilator associated pneumonia known or suspected to be caused by MRSA (methicillin resistant *Staphylococcus aureus*) on May 19, 2011(European time). VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable. VIBATIV is a bactericidal, once-daily injectable lipoglycopeptide antibiotic discovered by Theravance.

The CHMP, on the basis of quality, safety and efficacy data submitted, considered there to be a favourable benefit to risk balance for VIBATIV and therefore recommended the granting of the marketing authorisation.

The CHMP's positive opinion is a critical step in the approval process, and it is expected that the European Commission will follow the advice of the CHMP and grant marketing authorisation in approximately two to three months. If approved, it would allow Astellas to make the product available to healthcare professionals trying to meet the challenge of treating serious hospital-acquired lung infections caused by MRSA.

"*This positive opinion from the CHMP for VIBATIV is great news for both doctors and patients who continue to battle serious life-threatening nosocomial pneumonia, including ventilator associated pneumonia caused by MRSA," said Ken Jones, President and CEO, APEL. "It means health care professionals will soon have a new, effective hospital antibiotic with potent bactericidal activity against Gram-positive bacteria and potentially a higher likelihood of generating successful clinical outcomes in certain critically ill patients who increasingly fail to respond to established therapy*[1]," he added.

The European Centre for Disease Prevention and Control (ECDC) estimate that each year more than 4 million patients in Europe acquire an infection in hospital. At least 37,000 Europeans die as a direct result of hospital-acquired infections.[2] Risk factors for contracting a hospital-acquired infection due to MRSA include older age, prolonged hospitalisation, intravenous drug use and diabetes.[3] MRSA is the most frequent cause of ventilator-associated pneumonia and the second highest cause of mortality in these critically ill patients.[4]

Across Europe there is an high unmet need for new drugs which are active against MRSA and other Gram-positive pathogens particularly with poor susceptibility to more commonly used antibacterials[5].

VIBATIV, licensed from Theravance, Inc. for global commercialisation, is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action against Gram-positive bacteria including resistant pathogens such as MRSA[6,7].In Phase 3 clinical trials, more than 750 patients with nosocomial pneumonia, including a subset of patients with ventilator associated pneumonia, have been treated with VIBATIV.

In phase 3 clinical trials ATTAIN I & and ATTAIN II VIBATIV has demonstrated non-inferiority to vancomycin in the primary endpoint of clinical cure, with better outcomes in certain patient populations. [7-9]

VIBATIV was approved in the United States since 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.[10]

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 over 750,000 patients worldwide.[11] 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 III 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.[12]

-ENDS-

About Astellas Phama 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 organization 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.

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 3,900 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

####

Contacts for inquiries or additional information

Astellas Pharma Inc. (Japan)
Corporate Communications
Tel: +81-3-3244-3201 Fax: +81-3-5201-7473
http://www.astellas.com/en

Contacts for inquiries or additional information

Astellas Pharma Europe Ltd (UK)
Corporate Communications
Dooa Mindy
Tel: +44 (0)1784 419408
http://www.astellas.eu

1. Matteo Bassetti M, Mikulska M, Righi E et al. The role of telavancin in the treatment of MRSA infections in hospital. Expert Opin Investig. Drugs 2009; 18:521-529
2. European Centre for Disease Control: http://ecdc.europa.eu/en/healthtopics/healthcare-associated_infections/pages/index.aspx. Accessed 17 May 2011
3. Ratnaraja & Hawley. Current challenges in treating MRSA: what are the options*? Expert Rev Anti Infect Ther* 2008;**6**:601–18.
4. Kollef MH, Morrow LE, Niederman MS *et al*. Clinical Characteristics and Treatment Patterns Among Patients with Ventilator-Associated Pneumonia.*Chest* 2006;**129**:1210–8
5. ECDC/EMEA Joint Technical Report: The bacterial challenge: time to react. 17 September 2009. http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf Accessed 17 May 2011
6. Higgins DL, Chang R, Debabov DV, *et al.* Telavancin, a multifunctional lipoglycopeptide, disrupts both cell wall synthesis and cell membrance integrity in methicillin-resistant *Staphylococcus aureus. Antimicrob. Agents Chemother* 2005;49:1127-1134
7. Rubinstein 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
8. Shorr AF, Niederman M, Kollef MH, *et al*. Telavancin: a novel agent for ventilator-associated pneumonia due to Staphylococcus aureus. Oral presentation at the Annual Meeting of the ACCP; *Chest* 2008, abstract.
9. Rubinstein, E, Barriere, SL, Gente*r, FC*, *et al*. Late ventilator-associated pneumonia (VAP): analysis of baseline characteristics and clinical outcomes in the ATTAIN studies. Poster 823. *SCCM 2*010
10. VIBATIV US prescribing information May 20*11*
11. *IM*S Midas sales 12/02 to 12/10, Astellas Pharma Lt*d*
12. Astellas press release on partnership with Optimer for fidaxomicin, 7th Feb 2011