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News Release

October 24, 2008

Astellas Announces the Withdrawal of EU MAA for Telavancin for Complicated Skin and Soft Tissue Infections

Japan, October 24, 2008 - Astellas Pharma Inc. (Astellas) announced today it has withdrawn a European marketing authorisation application (MAA) for telavancin, a bactericidal, once-daily injectable investigational antibiotic with a multifunctional mechanism of action, for the treatment of complicated skin and soft tissue infections (cSSTI).

Astellas' European subsidiary, Astellas Pharma Europe B.V., submitted the MAA for telavancin for cSSTI in adults to the European Medicines Agency (EMEA) on April 27, 2007. Astellas has withdrawn the MAA based on communications from the Committee for Medicinal Products for Human Use (CHMP) of the EMEA that the data provided are not sufficient to allow the Committee to conclude a positive benefit-risk balance for telavancin for the sole indication of cSSTI at this time. Astellas currently intends to prepare a new MAA with expanded clinical trial data that was not available at the time of the initial application, including data from the hospital-acquired pneumonia Phase 3 studies.

Telavancin is also under review for marketing approval by regulatory authorities in the United States for the treatment of complicated skin and skin structure infections (cSSSI). The Anti-Infective Drugs Advisory Committee (AIDAC) to the U.S. Food and Drug Administration (FDA) will convene on November 19, 2008 to review the New Drug Application (NDA) for telavancin for the proposed indication to treat cSSSI caused by Gram-positive bacteria, including resistant pathogens such as methicillin-resistant Staphylococcus aureus (MRSA).

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