European Medicines Agency
Press office

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PRESS RELEASE
Astellas withdraws its marketing authorisation application for Vibativ (telavancin)

The European Medicines Agency (EMEA) has been formally notified by Astellas Pharma Europe B.V. of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Vibativ (telavancin) 15 mg/ml powder for concentrate for solution for infusion.

Vibativ was expected to be used for the treatment of complicated skin and soft tissue infections in adults.

The application for marketing authorisation for Vibativ was submitted to the EMEA on 2 May 2007. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Vibativ was based on the CHMP's communication that the data provided were not sufficient to allow it to conclude a positive benefit-risk balance for Vibativ for the applied indication at that time.

More information about Vibativ and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

-- ENDS --

Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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