European Medicines Agency
Press office

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PRESS RELEASE

Pfizer withdraws its marketing authorisation application for Exulett (dalbavancin)

The European Medicines Agency (EMEA) has been formally notified by Pfizer of its decision to withdraw its application for a centralised marketing authorisation for the medicine Exulett (dalbavancin), 500 mg powder for concentrate for solution for infusion. Exulett was expected to be used for complicated skin and soft tissue infections in adults when known or suspected to be caused by susceptible Gram-positive bacteria.

The application for marketing authorisation for Exulett was submitted to the EMEA on 26 July 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 Exulett was based on its decision to conduct a second phase III clinical trial of dalbavancin in the treatment of complicated skin and soft tissue infections due to Gram-positive bacteria. This study is intended to generate additional clinical data to support planned future regulatory filings globally.

More information about Exulett 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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