



European Medicines Agency
Press office

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PRESS RELEASE

Targanta Netherlands B.V. withdraws its marketing authorisation application for Ramvocid (oritavancin)

The European Medicines Agency has been formally notified by Targanta Netherlands B.V. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ramvocid (oritavancin), 100 mg powder for solution for infusion.

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

The application for the marketing authorisation for Ramvocid was submitted to the Agency on 20 May 2008. 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 the application was based on the CHMP's view that the data provided did not allow the Committee to conclude on a positive benefit-risk balance for Ramvocid.

More information about Ramvocid 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 Agency's website after the next CHMP meeting on 21-24 September 2009.

-- 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 European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

Media enquiries only to:

Monika Benstetter

Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu