EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Janssen-Cilag International NV withdraws its application for an extension of the indication for Velcade (bortezomib)

The European Medicines Agency has been formally notified by Janssen-Cilag International NV of its decision to withdraw its application for an extension of the therapeutic indication for the centrally authorised medicine Velcade (bortezomib).

On 2 September 2011, Janssen-Cilag International NV submitted an application to extend the marketing authorisation for Velcade in combination with rituximab for the treatment of patients with relapsed follicular non-Hodgkin lymphoma. At the time of the withdrawal the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Velcade was first authorised in the European Union on 26 April 2004 and is indicated in combination with melphalan and prednisone to treat patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with a bone marrow transplant. Velcade is also indicated as monotherapy to treat progressive multiple myeloma in patients who have received at least one prior therapy and have already had or are unsuitable for a bone marrow transplant.

In its official letter, the company stated that it decided to withdraw the application after the CHMP indicated that the data provided do not support a positive benefit-risk balance.

Velcade continues to be authorised in the currently approved indications.

More information about Velcade and the state of the scientific assessment at the time of the 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 16-19 July 2012 CHMP meeting.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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