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Press Office

Press release

Merck Sharp and Dohme Ltd. withdraws its marketing authorisation application for Jenzyl (ridaforolimus)

The European Medicines Agency has been formally notified by Merck Sharp and Dohme Ltd. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Jenzyl (ridaforolimus), 10 mg tablets. Jenzyl was intended to be used for the treatment of patients with metastatic soft tissue sarcoma or bone sarcoma as a maintenance therapy.

The application for the marketing authorisation for Jenzyl was submitted to the Agency on 25 June 2011. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its withdrawal letter, the company stated that it has decided to withdraw the application since the CHMP considers that the data provided do not allow the Committee to conclude on a positive benefit-risk balance.

More information about Jenzyl 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 CHMP meeting of 10-13 December 2012.

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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