European Medicines Agency
Press office

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PRESS RELEASE
Bristol-Myers Squibb Pharma EEIG withdraws its marketing authorisation application for Ixempra (ixabepilone)

The European Medicines Agency has been formally notified by Bristol-Myers Squibb Pharma EEIG of its decision to withdraw the application for a centralised marketing authorisation for Ixempra (ixabepilone), 2 mg/ml powder and solvent for concentrate for solution for infusion.

Ixempra was expected to be used to treat locally advanced or metastatic breast cancer after failure of previous cytotoxic chemotherapy treatments. It was to be used in combination with capecitabine.

The application for the marketing authorisation for Ixempra was submitted to the Agency on 24 September 2007. On 20 November 2008, the Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation. Following this, the company requested a re-examination of the opinion, which was under review by the CHMP at the time of the withdrawal.

The company stated in its official letter that the withdrawal of application for Ixempra was based on the fact that the information provided in the re-examination procedure did not provide the Committee with sufficient evidence to change the benefit-risk balance.

More information about the withdrawal of Ixempra 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 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. More information about the negative opinion is available in a question-and-answer document.
3. 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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