European Medicines Agency
Press office

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PRESS RELEASE
Bioenvision Ltd withdraws its application for an extension of indication for Evoltra (clofarabine)

The European Medicines Agency (EMEA) has been formally notified by Bioenvision Ltd, a wholly owned subsidiary of Genzyme Corporation, of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Evoltra (clofarabine).

Evoltra was expected to be used for the treatment of acute myeloid leukaemia in elderly patients.

Evoltra was first authorised in the European Union on 29 May 2006. It is currently indicated for the treatment of acute lymphoblastic leukaemia in paediatric patients.

The application for the extension of indication for Evoltra was submitted to the EMEA on 7 February 2007. In its official letter, the company stated that the withdrawal of the application was based on the CHMP's opinion that the data provided did not allow the Committee to conclude that the benefits of the medicine outweigh the risks. However, data could be provided in order to support a resubmission in this indication in the near future.

More information about Evoltra 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 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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