EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

ChemGenex Europe SAS withdraws its marketing authorisation application for Tekinex (omacetaxine mepesuccinate)

The European Medicines Agency has been formally notified by ChemGenex Europe SAS of its decision to withdraw its application for a centralised marketing authorisation for Tekinex (omacetaxine mepesuccinate), 5 mg powder for solution for injection.

This medicine was intended to be used for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia (CML) who have the Bcr-Abl T315I kinase domain mutation and who are resistant to prior imatinib therapy.

The application for the marketing authorisation for Tekinex was submitted to the Agency on 30 October 2009. 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 they decided to change the proposed indication of Tekinex to the treatment of adults with CML who have failed prior treatment with two or more currently approved tyrosine kinase inhibitors (TKIs). The company further stated that they were unable to address the issues identified by the CHMP within the timeframe allowed in the centralised procedure. Due to the amount of time required to address the issues identified by the CHMP and assemble the clinical data package supporting the changed indication the company decided to withdraw the ongoing application.

More information about Tekinex 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 17-20 January 2011.

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 the company making a new application at a later stage.

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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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