European Medicines Agency
Press office

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PRESS RELEASE
Oncoscience AG withdraws its application for Theraloc (nimotuzumab)

The European Medicines Agency (EMEA) has been formally notified by Oncoscience AG of its decision to withdraw its application for a centralised marketing authorisation for the medicine Theraloc (nimotuzumab), 5 mg/ml concentrate for solution for infusion.

Theraloc was expected to be used to treat children and adolescents with resistant or recurrent high-grade glioma. Theraloc was designated as an orphan medicine on 2 September 2004.

The application for the marketing authorisation for Theraloc was submitted to the EMEA on 4 October 2007. 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 the withdrawal of the application was made because it was not able to adequately address the concerns of the CHMP regarding the quality and efficacy of the medicine within the required time schedule.

More information about Theraloc 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 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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