DR. REGENOLD GmbH
International Regulatory Affairs

Dr. Eric Abadie
European Medicines Agency
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Canary Wharf
London E14 4HB
UK

Subject: Withdrawal of Theraloc (nimotuzumab), 5 mg/ml concentrate for solution for infusion – **EMEA/C/H/000931**

Badenweiler, 01.12.2008

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Oncoscience AG has taken the decision to withdraw the application for Marketing Authorisation of Theraloc, (nimotuzumab), 5 mg/ml concentrate for solution for infusion, which was intended to be used for treatment of children and adolescents with resistant or recurrent high-grade glioma.

This withdrawal is based on the following considerations:
In connection with the examination of the Marketing Authorisation Application (MAA) for Nimotuzumab, CHMP has raised a series of questions/objections as to the validity of the product quality and efficacy (see 180 day questions). The applicant is not in a position to adequately address these major CM & C concerns as raised by CHMP within the required time schedule, in particular since the inspection of the manufacturing and control facilities at the Centre of Molecular Immunology (CIM) requested in accordance with the Regulation (EC) No.726/2004, article 8 (2) could not be performed as scheduled.

The applicant intends to continue the development of the product and in this context reassess the dossier, gather additional data and supportive evidences prior to resubmission.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

We agree for this letter to be published on the EMEA website, however, any commercially confidential information should be deleted. Please contact me if further information is needed.

Yours sincerely

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