

## European Medicines Agency Pre-Authorisation Evaluation of Medicines for Human Use

London, 29 May 2009 Doc.Ref. EMEA/CHMP/291093/2009

## COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE SUMMARY OF POSITIVE OPINION\* for

## **TOPOTECAN ACTAVIS**

International Nonproprietary Name (INN): topotecan

On 29 May 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,\*\* recommending to grant a marketing authorisation for the medicinal product Topotecan Actavis, 1 mg and 4 mg, powder for concentrate for solution for infusion intended for the treatment of patients with relapsed small cell lung cancer for whom re-treatment with the fine-line regimen is not considered appropriate; and in combination with cisplatin Topotecan Actavis, is intended for the treatment of patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustain d treatment free interval to justify treatment with the combination. The applicant for this medicinal product is Actavis Group PTC ehf.

The active substance of Topotecan Actavis is topotecan (as typ ochloride), an antineoplastic and immunomodulating agent (L01XX17). Topotecan is a cytoloxic anti-cancer agent and acts by inhibition of the nuclear enzyme topoisomerase I that is involved in DNA replication. As a result, DNA damage induces apoptotic cell death predominantly in replicating cells such as tumour cells.

Topotecan Actavis is a generic of Hycamtin, which has been authorised in the EU since 12 November 1996. Studies have demonstrated the satisfactory quality of Topotecan Actavis. Topotecan Actavis is administrated intravenously and is 100% by available. Therefore, a bioequivalence study versus the reference medicinal product was not required. A question-and-answer document on generic medicines can be found here.

The approved indication is:

"Topotecan monotherapy is indicated for the treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatmen with the first-line regimen is not considered appropriate.

Topotecan in combination with cisplatin is indicated for patients with carcinoma of the cervix recurrent after radiotle a py and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination."

A pharmacovigilance plan for Topotecan Actavis, as for all medicinal products, will be implemented as part of the prarketing authorisation.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and wing a available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Topotecan Actavis and therefore recommends the granting of the marketing authorisation.

\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.