The European Agency for the Evaluation of Medicinal Products
Pre-Authorisation Evaluation of Medicines for Human Use

London, 20 November 2003
CPMP/5706/03

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for
YONDELIS

International Nonproprietary Name (INN): **trabectedin**

On 24 July 2003 the Committee for Proprietary Medicinal Products (CPMP) adopted a negative opinion, recommending not to grant a marketing authorisation for the medicinal product Yondelis, 0.25 mg and 1 mg, powder for concentrate for solution for infusion intended for patients with advanced soft tissue sarcoma (STS), having failed anthracyclines and ifosfamide, or having failed ifosfamide and unsuitable to receive anthracyclines. Yondelis was designated as an orphan medicinal product on 30 May 2001 (EU/3/01/039). The applicant for this medicinal product is Pharma Mar S.A.

The active substance of Yondelis is trabectedin, a new anti-cancer medicinal product (antineoplastic agent - L01CX01).

The detailed grounds for appeal against the initial CPMP opinion on 24 July 2003 where received from the applicant on 26 September 2003.

Following the assessment of the grounds for appeal submitted by the Applicant and having asked advice from the EMEA/CPMP therapeutic advisory group in oncology that met at the EMEA on 17 November 2003, the CPMP concluded the appeal process on 20 November 2003. The CPMP in its conclusion confirmed its earlier recommendation to refuse a marketing authorisation on the following grounds:

There remained critical concerns on the methodology used and the resulting potential bias, and there remained considerable uncertainty about the level of response rate and progression-free survival and overall survival rates of trabectedin in the proposed indication, so that the efficacy of trabectedin in the proposed indication could not be established. The Committee acknowledged that it is difficult to conduct clinical trials in soft tissue sarcoma and that the data presented included a large series of patients in the context of this rare disease.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that the unfavourable benefit to risk balance for Yondelis remains - as in the opinion of 24 July 2003 - and therefore cannot recommend the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

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