



European Medicines Agency
Evaluation of Medicines for Human Use

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

International Nonproprietary Name (INN): *mifamurtide*

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product MEPACT, 4 mg, powder for suspension for infusion, intended for the treatment of osteosarcoma. MEPACT was designated as an orphan medicinal product on 21 June 2004. The applicant for this medicinal product is IDM Pharma, S.A.

The active substance of MEPACT is mifamurtide, an immunomodulator (ATC code: L03AX15). Mifamurtide activates monocytes and macrophages and this may be the mechanism responsible for its antitumour activity.

The benefits with MEPACT when used in conjunction with combination chemotherapy are its effect in terms of overall survival, as observed in a randomised controlled trial when compared to chemotherapy alone. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis. The most common side effects were anaemia, anorexia, headache, dizziness, tachycardia, hypertension, hypotension, dyspnoea, tachypnoea, cough, vomiting, diarrhoea, constipation, abdominal pain, nausea, hyperhidrosis, myalgia, arthralgia, back pain, pain in extremity, fever, chills, fatigue, hypothermia, pain, malaise, asthenia, and chest pain.

A pharmacovigilance plan for MEPACT, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “MEPACT is indicated in children, adolescents and young adults for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection. It is used in combination with post-operative multi-agent chemotherapy. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis”.

It is proposed that MEPACT treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of osteosarcoma.

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 will be 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 MEPACT 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.