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

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
TEPADINA

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

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Tepadina, 15mg and 100mg, powder for concentrate for solution for infusion intended as conditioning treatment prior to autologous or allogeneic haematopoietic progenitor cell transplantation in adult and paediatric patients. Tepadina was designated as an orphan medicinal product on 29 January 2007. The applicant for this medicinal product is ADIENNE S.r.l..

The active substance of Tepadina is thiotepa, an ethylene imine medicinal product (L01AC01), which is a cell cycle-phase independent, non-specific alkylating antineoplastic agent, related chemically and pharmacologically to the nitrogen mustard.

The benefits with Tepadina are its cytotoxic and myeloablative ability which are applied to conditioning treatment prior to haematopoietic stem cell transplantation. The most common side effects are infections, pancytopenia, gastrointestinal disorders, haemorrhagic cystitis and mucosal inflammation.

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

The approved indication is: “in combination with other chemotherapy medicinal products: 1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; 2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.”. It is proposed that Tepadina must be prescribed by physicians experienced in conditioning treatment prior to haematopoietic progenitor cell transplantation.

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 Tepadina and therefore recommends the granting of the marketing authorisation.

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* 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.

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