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

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
JAVLOR

International Nonproprietary Name (INN): ***vinflunine ditartrate***

On 25 June 2009the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Javlor, 25 mg/ml, concentrate for solution for infusion, intended for treatment of transitional cell carcinoma of the urothelium. The applicant for this medicinal product is Pierre Fabre Médicament.

The active substance of Javlor is vinflunine ditartrate, a vinca alkaloid therapeutic class medicinal product (ATC Code L01CA05) which mainly acts as a mitotic spindle poison to impair chromosomal segregation during mitosis. Vinflunine ditartrate blocks cells at the G2/M phase of the cell cycle and induces cell death via apoptosis. It interacts with tubulin at the vinca-binding domain and inhibits tubulin assembly by perturbing microtubule dynamics and mitotic spindles.

The benefits with Javlor are those of clinical efficacy compared to best standard of care alone, as observed in secondary analyses of a randomised clinical trial in patients with advanced or metastatic transitional cell carcinoma of the urothelium, as second-line therapy after failure of a prior platinum-containing regimen. The most common side effects are abdominal pain, nausea, vomiting; constipation, diarrhoea; inflammation of the mucosa of the mouth; fatigue, muscle pain; weight decrease, loss of appetite; loss of hair; pain at the site of injection; decrease in the number of white blood cells (neutropenia) or red blood cells (anaemia) or platelets, and fever.

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

The approved indication is: "Javlor is indicated in monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen. Efficacy and safety of vinflunine have not been studied in patients with Performance Status ≥ 2". It is proposed that vinflunine treatment should be initiated under the responsibility of a physician qualified in the use of anticancer chemotherapy.

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 Javlor 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 8613
E-mail: mail@emea.europa.eu http://www.emea.europa.eu