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

London, 29 May 2009
Doc.Ref. EMEA/CHMP/285157/2009

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

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

On 28 May 2009 the Committee for Medicinal Products for Human Use (CHMP), having considered new information, adopted a positive opinion,*** recommending to grant a marketing authorisation for the medicinal product Samsca, 15 mg and 30 mg tablets intended for the treatment of hyponatraemia. The Applicant for this medicinal product is Otsuka Pharmaceutical Europe Ltd.

The active substance of Samsca is tolvaptan, a vasopressin antagonist medicinal product (C03XA01) which blocks the binding of arginine vasopressin at the V_2 receptors of the distal portions of the nephron, thereby inducing free water clearance (aquaresis) without depletion of electrolytes.

The benefits with Samsca are the improvement of serum sodium balance for the duration of therapy and the prevention of progressive lowering of sodium. This correction of hyponatraemia offers a clinically relevant effect which has been shown in patients with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH). The most common side effects are nausea and thirst. Teratogenicity seen in animal studies is addressed by a contraindication in pregnancy.

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

The approved indication is: "Treatment of adult patients with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH)". Due to the need for a dose titration phase with close monitoring of serum sodium and volume status, treatment with Samsca should be initiated in hospital.

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 Samsca 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.

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