European Medicines Agency
Evaluation of Medicines for Human Use

London, 30 July 2007
EMEA/CHMP/247760/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(4)[1] REFERRAL FOR

Vantas

International Non-Proprietary Name (INN): Histrelin acetate

BACKGROUND INFORMATION

Vantas, 50 mg, implant, is a luteinizing hormone-releasing hormone (LHRH) agonist indicated for the palliative treatment of advanced prostate cancer.

Valera Pharmaceuticals Ltd. submitted applications for mutual recognition of Vantas, 50 mg, implant, on the basis of the marketing authorisation granted by Denmark on 17 November 2005. The Mutual Recognition Procedure started on 23 August 2006. The Reference Member State was Denmark and the Concerned Member States were Germany, Spain, Ireland, Italy and the United Kingdom. These Member States were not able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. Germany, Spain, Ireland, Italy and the United Kingdom referred the reasons for disagreement to the EMEA on 1 February 2007.

The reasons for disagreement was that, according to some Member States, the efficacy of Vantas was not demonstrated in comparison to other approved, effective treatments and that the safety of Vantas also was not adequately demonstrated.

The arbitration procedure started on 22 February 2007 with the adoption of a list of questions. The Rapporteur was Dr Frits Lekkerkerker and Co-Rapporteur(s) was Dr Jens Ersbøll. The Marketing Authorisation Holder provided written explanations on 7 March 2007.

During their May 2007 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Vantas, that the objections raised by Germany, Spain, Ireland, Italy and the United Kingdom should not prevent the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was adopted by consensus on 24 May 2007.

The list of the product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the Summary of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 30 July 2007.

[1] Article 29(4) of Directive 2001/83/EC, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu