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

London, 18 December 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
FIRMAGON

International Nonproprietary Name (INN): ***degarelix (as acetate)***

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 Firmagon, 80 mg and 120 mg, powder and solvent for solution for injection, intended for the treatment of prostate cancer. The applicant for this medicinal product is Ferring Pharmaceuticals A/S.

The active substance of Firmagon is degarelix, a gonadotropin-releasing hormone receptor antagonist medicinal product (ATC code: L02BX02). Degarelix binds to receptors in the anterior pituitary gland and this results in a decreased secretion of luteinizing hormone and follicle-stimulating hormone and subsequently decreased production of the steroid hormone testosterone, which is necessary for growth and spread of prostate cancer cells.

The benefits with Firmagon are its achievement and maintenance of very low levels of testosterone ($\leq$ 0.5 ng/ml) throughout the 12-month treatment period without an initial surge in testosterone, as observed in a randomised clinical trial comparing two different degarelix dosing regimens to leuprorelin in patients with prostate cancer requiring androgen deprivation therapy. The most common side effects are hot flushes, injection site pain, injection site erythema, increased weight, nasopharyngitis, fatigue, and back pain.

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

The approved indication is: "Firmagon is a gonadotrophin releasing hormone (GnRH) antagonist indicated for treatment of adult male patients with advanced hormone-dependent prostate cancer".

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 Firmagon 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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