25 April 2013
EMA/CHMP/231975/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xtandi

enzalutamide

On 25 April 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xtandi, 40 mg, soft capsule, intended for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy. The applicant for this medicinal product is Astellas Pharma Europe B.V.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xtandi is enzalutamide, a potent androgen receptor signalling inhibitor (ATC Code not yet assigned) that blocks several steps in the androgen receptor signalling pathway.

The benefits with Xtandi are its ability to improve the survival of patients and to delay the progression of disease. The most common side effects are hot flush and headache.

A pharmacovigilance plan for Xtandi will be implemented as part of the marketing authorisation.

The approved indication is: "Xtandi is indicated for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made 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 there to be a favourable benefit-to-risk balance for Xtandi and therefore recommends the granting of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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