17 January 2013
EMA/CHMP/5734/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jetrea

ocriplasmin

On 17 January 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 Jetrea, 0.5mg/0.2mL, concentrate for solution for injection intended for the treatment of adults with an eye disease called vitreomacular traction (VMT), including when it is associated with a small hole in the macula (central part of the light-sensitive layer at the back of the eye). The applicant for this medicinal product is ThromboGenics NV. 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 Jetrea is ocriplasmin, for which a therapeutic group has not yet been assigned. Ocriplasmin has a proteolytic activity against protein components of the vitreous body and the vitreoretinal interface (VRI) (e.g. laminin, fibronectin and collagen) and aims to dissolve the protein matrix responsible for the abnormal vitreomacular adhesion (VMA). The tight binding of the protein components within the macular area of the VRI contribute to vitreomacular traction (VMT), leading to visual impairment and/or macular holes.

The benefits with Jetrea are its ability to release the traction between the vitreous and the macula through its proteolytic activity, with the potential to prevent further damage to the vision and a need for vitrectomy in a small percentage of patients. The most common side effects are vitreous floaters, eye pain and photopsia, as well as conjunctival haemorrhage resulting from the injection procedure.

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

The approved indication is: Jetrea is indicated in adults for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns. Jetrea must be prepared and administered by a qualified ophthalmologist experienced in intravitreal injections.

[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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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 Jetrea and therefore recommends the granting of the marketing authorisation.