EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends approval of medicine for treatment of vitreomacular traction

Jetrea is the first non-surgical treatment option for this condition

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Jetrea, a medicinal product indicated for the treatment of adults with vitreomacular traction (VMT), an eye condition which can cause severe visual disturbance. Jetrea represents the first medicinal option for patients suffering from this condition.

With ageing, the vitreous humour of the eye undergoes shrinkage which can result in a pulling force on the area of the retina called the macula (vitreomacular traction), which is responsible for central and colour vision. This can cause decreased vision and the distortion and shrinkage of images, and is a risk factor for the development of macular holes.

Jetrea addresses an unmet medical need. The only active treatment option currently available for VMT is surgery (vitrectomy), whereby the vitreous humour is removed. The post-vitrectomy patient may have to undergo a period of 4-6 weeks without being able to work or live normally, out of which 7-14 days may be in a 'head-down' position to enhance the success rate of the surgical procedure. This 'head-down' posturing can be very inconvenient for the patient, and carries a significant burden of care to family or friends.

Jetrea contains the new active substance ocriplasmin, a recombinant human protein derived from the yeast *Pichia pastoris*. Ocriplasmin has enzymatic activity against proteins in the interface between the vitreous humour and the retina. By breaking down these proteins, ocriplasmin can loosen the adhesion between the vitreous humour and the macula and can therefore resolve traction at the macula.

The CHMP has recommended the approval of Jetrea for the treatment of VMT, including when associated with a macular hole of diameter less than or equal to 400 microns. The recommended dose is 125 micrograms administered by intravitreal injection to the affected eye once as a single dose. As part of the conditions and requirements for marketing authorisation, the CHMP is requiring the marketing-authorisation holder to provide all healthcare professionals who are expected to use Jetrea with information packs for patients in addition to the summary of product characteristics.

The applicant for Jetrea is ThromboGenics N.V. The company received scientific advice from the Agency with regard to the assessment of Jetrea. In addition, as ThromboGenics is an SME (micro,

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small or medium-sized enterprise), it benefited from administrative and procedural assistance from the Agency prior to licensing the product to a commercial partner. The Agency put in place the SME initiative in 2005 to promote innovation and development of medicines by SMEs, as it recognises that SMEs are a major driver of innovation in the pharmaceutical industry.

The CHMP opinion on Jetrea will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Further information on the Agency's SME Office can be found at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000059.jsp&mid=WC0b01ac05800240cc
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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