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Recommendation for maintenance of orphan designation at the time of marketing authorisation

Oxervate (cenegermin) for the treatment neurotrophic keratitis

On 19 May 2017, the Committee for Orphan Medicinal Products (COMP) completed its review of the designation EU/3/15/1586 for Oxervate (cenegermin, previously known as recombinant human nerve growth factor) as an orphan medicinal product for the treatment neurotrophic keratitis. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained[1].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Oxervate for: 'treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults'.

This falls within the scope of the product's designated orphan indication, which is: 'neurotrophic keratitis'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2015. Neurotrophic keratitis remains a condition that is debilitating in the long term because of the damage to the eye's surface and possible loss of sight.

Prevalence of the condition

The sponsor provided an updated calculation of the prevalence of neurotrophic keratitis based on the prevalence of the conditions that can predispose to or cause neurotrophic keratitis.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of neurotrophic keratitis remains below the ceiling for orphan

[1] The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with the same therapeutic indication cannot be placed on the market.

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designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was estimated to be less than 4.1 people in 10,000. This is equivalent to a total of fewer than 211,000 people in the EU.

Existence of other methods of treatment

The COMP noted that, at the time of the review of the orphan designation, no treatments were authorised in the EU for neurotrophic keratitis.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Oxervate still meets the criteria for designation as an orphan medicinal product and that it should remain in the Community Register of Orphan Medicinal Products.

More information on the COMP assessment can be found in the May 2017 COMP minutes.

Further information on Oxervate can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find medicine/Human medicines/European public assessment reports.