EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

New medicine for rare eye disease

Oxervate reviewed under accelerated assessment

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Oxervate (cenegermin) for the treatment of moderate or severe neurotrophic keratitis, a rare eye disease that can lead to loss of sight.

Patients with neurotrophic keratitis have damage to the trigeminal nerve (one of the nerves that supplies the eye). This results in reduced or lack of sensation in the cornea (the clear layer at the front of the eye), and reduced production of the substances that play an important role in repairing damage and ensuring survival of cornea cells.

Oxervate is a copy of a human growth factor called nerve growth factor. When given as eye drops to patients with neurotrophic keratitis, it is expected to help restore some of the normal healing processes in the eye and repair the damage to the cornea.

There is currently no satisfactory treatment for neurotrophic keratitis. Depending on the stage of their disease, patients may be given eye drops to moisten the eye, antibiotics for eye infections, and protective contact lenses. Where appropriate, they may undergo surgery.

Oxervate is produced by 'recombinant DNA technology'. It is made by bacteria into which a gene (DNA) has been introduced, that enables the bacteria to produce human nerve growth factor.

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on data from two phase II clinical trials in 204 patients with moderate and severe neurotrophic keratitis. Both studies showed that after eight weeks, more patients treated with Oxervate achieved complete corneal healing than those treated with placebo.

The most common adverse reactions observed with Oxervate included eye pain, eye inflammation, increased lacrimation (secretion of tears), eyelid pain and a foreign-body sensation in the eye.

Neurotrophic keratitis only affects a small number of patients, and to encourage development of a treatment, Oxervate received an orphan designation from EMA's Committee for Orphan Medicinal Products (COMP) in 2015, with the consequent incentives including free scientific advice on the clinical and non-clinical aspects of the medicine's dossier. Once the application was made, the Agency reviewed it under its accelerated assessment programme, designed to facilitate access to medicines that meet an unmet medical need.

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The opinion adopted by the CHMP at its May 2017 meeting is an intermediary step on Oxervate's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Oxervate is Dompé farmaceutici S.p.A.
3. Following this positive CHMP opinion, the COMP will assess whether the orphan designation should be maintained.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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