EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

New medicine for rare form of eye allergy in children and teenagers

Verkazia approved under accelerated assessment

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Verkazia (ciclosporin), a medicine that treats severe vernal keratoconjunctivitis (VKC), a rare form of chronic eye allergy that can lead to corneal ulcers and loss of sight, in children from four years of age and adolescents.

VKC (also known as spring catarrh) is characterised by chronic inflammation of the conjunctiva (membrane lining the eyelid and covering the eyeball) and the cornea (clear tissue in the front of the eye that protects deeper structures). This leads to redness, fluid discharge, itching, pain and light sensitivity. Severe and chronic forms of the disease, if left untreated, can result in complications leading to irreversible vision loss. VKC occurs mostly in young children and teenagers with other allergic conditions, such as eczema and asthma.

There is a need for additional treatments because currently authorised therapies are not always effective or adequate to control severe VKC. For instance, corticosteroids, a class of steroid hormones, are often used in moderate to severe disease with persistent symptoms but the side effects when taken for a prolonged period, including formation of cataracts, are a major limitation of this treatment choice. Verkazia offers an alternative treatment approach based on eye drops containing ciclosporin, which regulate the immune system to limit the progress of autoimmune conditions such as allergies.

The recommendation of EMA's Committee for Medicinal Products for Human Use (CHMP) is mainly based on data from one phase III clinical trial in 169 patients with severe VKC. The study showed that, after four months, more patients treated with Verkazia than with placebo had an improvement in corneal health while requiring no additional corticosteroid medication. After four months of treatment, all main VKC symptoms studied (light sensitivity, itching, tearing and mucous discharge) improved.

Very few patients suffer from VKC: 1 to 3 people out of 10,000 in the European Union (EU), according to Eurostat. To encourage its development, Verkazia received an orphan designation from the Committee for Orphan Medicinal Products (COMP) in April 2006, with the resulting incentives including free scientific advice on the clinical and non-clinical aspects of the medicine's development.

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As always at time of approval, this orphan designation will now be reviewed to determine whether the information available to date allows maintaining Verkazia's orphan status and granting this medicine 10 years of market exclusivity.

The Agency reviewed the application under its accelerated assessment mechanism.

The opinion adopted by the CHMP at its July 2017 meeting is an intermediary step on Verkazia'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 Verkazia is Santen Oy from Finland.
3. Following this positive CHMP opinion, the Committee for Orphan Medicinal Products (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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