18 October 2018
EMA/700432/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Takhzyro

lanadelumab

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Takhzyro, intended for the prevention of recurrent attacks of hereditary angioedema.

Takhzyro, which was designated as an orphan medicinal product on 9 October 2015, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Shire Pharmaceuticals Ireland Limited.

Takhzyro will be available as a 300-mg solution for injection. The active substance of Takhzyro is lanadelumab, a monoclonal antibody that inhibits active plasma kallikrein proteolytic activity (ATC code: B06AC05). Increased plasma kallikrein activity leads to angioedema attacks in patients with hereditary angioedema through the proteolysis of high-molecular-weight kininogen and bradykinin. Lanadelumab provides sustained control of plasma kallikrein activity and thereby limits bradykinin generation in patients with hereditary angioedema.

The benefit of Takhzyro is its ability to significantly reduce the mean hereditary angioedema attack rate compared with placebo. The percentage of patients who were attack free for the last 16 weeks of a controlled study was 77% in the group receiving 300 mg Takhzyro every 2 weeks, compared to 3% of patients in the placebo group.

The most common side effects are injection site reactions (including pain, erythema and bruising). Of these, 97% were of mild intensity.

The full indication is: "Takhzyro is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older".

It is proposed that Takhzyro be made available upon prescription and that treatment is initiated under the supervision of a physician experienced in the management of patients with hereditary angioedema.

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

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

available in all official European Union languages after the marketing authorisation has been granted by the European Commission.