12 December 2024
EMA/CHMP/511066/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Andembry

garadacimab

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Andembry[2], intended for the prevention of recurrent attacks of hereditary angioedema (HAE).

The applicant for this medicinal product is CSL Behring GmbH.

Andembry will be available as 200 mg solution for injection in pre-filled pen or syringe. The active substance in Andembry is garadacimab, a drug used in hereditary angioedema (ATC code: B06AC07). Andembry is a fully human, recombinant, IgG4 lambda monoclonal antibody that binds to the catalytic domain of activated factor XII (FXIIa). FXIIa is the first factor activated in the contact system, which leads to the production of bradykinin. The inhibition of FXIIa therefore prevents the activation of prekallikrein into kallikrein and the generation of bradykinin, which is associated with inflammation and swelling in HAE attacks.

The benefits of Andembry were shown in a study involving patients with HAE. Over 6 months of treatment, patients taking Andembry had a lower monthly rate of HAE attacks compared with patients given placebo. Additionally, more patients taking Andembry were attack-free during the first 3 months of treatment compared to placebo. The most common side effects with Andembry are injection site reactions including erythema, bruising and pruritus.

The full indication is:

> ANDEMBRY is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older.

Andembry should be prescribed by physicians experienced in the management of patients with HAE.

There are limited data available on the use of garadacimab in HAE patients with normal C1-esterase inhibitor (nC1-INH). Some subcategories of nC1-INH HAE may not respond to treatment with

[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.
[2] This product was designated as an orphan medicine during its development. At the request of the applicant, the medicine was removed from the Community Register of Orphan Medicinal Products on 25 November 2024.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

garadacimab due to alternative pathways that do not include FXII activation.

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