25 April 2025
EMA/CHMP/126704/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tepezza

teprotumumab

On 25 April 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tepezza, intended for the treatment of adults with moderate to severe thyroid eye disease.

The applicant for this medicinal product is Amgen Europe B.V.

Tepezza will be available as a 500 mg powder for concentrate for solution for infusion. The active substance of Tepezza is teprotumumab, a monoclonal antibody (ATC code: L04AG13), which binds to the insulin-like growth factor 1 receptor and inhibits its activity. This blocks the autoimmune activation of orbital fibroblasts, which is thought to help stop the development and progression of thyroid eye disease.

The benefits of Tepezza are reductions in protrusion of the eyeball from the eye socket (proptosis) and the clinical activity score (a standard tool to evaluate inflammatory signs and symptoms of thyroid eye disease) compared with placebo. These benefits were demonstrated in three phase 3 randomised, placebo-controlled trials in patients with active thyroid eye disease. A separate phase 3 randomised, placebo-controlled trial demonstrated reduction in proptosis in patients with chronic thyroid eye disease.

The most common side effects with Tepezza include spasms, diarrhoea, alopecia, hyperglycaemia, fatigue, nausea and headache. Some patients experienced hearing impairment. In addition, pre-clinical studies have shown that Tepezza may pose risks for the development of the fetus. Additional risk minimisation measures will be implemented to mitigate these risks.

The full indication is:

> Tepezza is indicated in adults for the treatment of moderate to severe thyroid eye disease (TED).

Treatment with Tepezza should be initiated and supervised by physicians experienced in the diagnosis and treatment of thyroid eye disease.

[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

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.