25 April 2025
EMA/127794/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zadenvi

denosumab

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 Zadenvi, intended for the treatment of osteoporosis in women who have been through menopause, treatment of bone loss linked to hormone ablation in men at increased risk of fractures or treatment of bone loss associated with long-term treatment with systemic glucocorticoid.

The applicant for this medicinal product is Zentiva k.s.

Zadenvi will be available as a 60 mg solution for injection. The active substance of Zadenvi is denosumab, a drug for the treatment of bone diseases (ATC code: M05BX04). Denosumab is a human monoclonal IgG2 antibody that targets the protein RANKL, which is essential for the formation, function and survival of osteoclasts, the cell type responsible for bone resorption. Denosumab binds to RANKL with high affinity and specificity, preventing the interaction between RANKL and RANK. This leads to a reduction in osteoclast numbers and function and a decrease in bone resorption in cortical and trabecular bones.

Zadenvi is a biosimilar medicinal product. It is highly similar to the reference product Prolia (denosumab), which was authorised in the EU on 26 May 2010. Data show that Zadenvi has comparable quality, safety and efficacy to Prolia. More information on biosimilar medicines can be found here.

The full indication is:

> Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral and hip fractures.
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> Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (see section 5.1). In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures.
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> Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult

[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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patients at increased risk of fracture (see section 5.1).

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.