21 March 2024
EMA/99825/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jubbonti

denosumab

On 21 March 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 Jubbonti, intended for the treatment of osteoporosis in women who have been through menopause and in men at increased risk of fractures whose bone loss is linked to hormone ablation or long-term treatment with systemic glucocorticoid.

The applicant for this medicinal product is Sandoz GmbH.

Jubbonti will be available as 60 mg solution for injection in pre-filled syringe. The active substance of Jubbonti 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.

Jubbonti 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 Jubbonti 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.

[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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Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult 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 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.