21 March 2024
EMA/CHMP/99814/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Wyost

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 Wyost, intended for the prevention of bone complications in adults with advanced cancer involving bone and for the treatment of adults and skeletally mature adolescents with giant cell tumour of bone.

The applicant for this medicinal product is Sandoz GmbH.

Wyost will be available as 120 mg solution for injection. The active substance of Wyost 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. Increased osteoclast activity stimulated by RANKL is a key mediator of bone destruction in metastatic bone disease. 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 and cancer-induced bone destruction.

Wyost is a biosimilar medicinal product. It is highly similar to the reference product Xgeva (denosumab), which was authorised in the EU on 13 July 2011. Data show that Wyost has comparable quality, safety and efficacy to Xgeva. More information on biosimilar medicines can be found here.

The full indication is:

> Prevention of skeletal related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone (see section 5.1).
>
> Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.