19 May 2011
EMA/CHMP/383964/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

XGEVA

denosumab

On 19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product XGEVA, 120 mg, solution for injection, intended for prevention of skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours. The applicant for this medicinal product is Amgen Europe B.V. (Amgen). They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of XGEVA is denosumab, a human monoclonal IgG2 antibody produced in a mammalian cell line (chinese hamster ovary) by recombinant DNA technology (ATC code: M05BX04*).* The protein target of this antibody, RANKL, is essential for the formation, function and survival of osteoclasts, the sole cell type responsible for bone resorption. Increased osteoclast activity, stimulated by RANKL, is a key mediator of bone destruction in metastatic bone disease. Denosumab targets and binds with high affinity and specificity to RANKL, preventing the RANKL/RANK interaction from occurring and resulting in reduced osteoclast numbers and function.

The benefit of XGEVA is in the prevention of skeletal-related events in adults with bone metastases from solid tumours resulting from its ability to decrease bone resorption and cancer-induced bone destruction. The most common side effects are dyspnoea, diarrhoea, hypocalcaemia, hypophosphataemia, tooth extraction, hyperhidrosis and osteonecrosis of the jaw.

A pharmacovigilance plan for XGEVA will be implemented as part of the marketing authorisation.

The approved indication is: “Prevention of skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours”.

XGEVA should be administered under the responsibility of a healthcare professional. 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

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

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for XGEVA and therefore recommends the granting of the marketing authorisation.

Furthermore, the CHMP agreed with the applicant´s request for the extension by 1 year of the marketing protection period for denosumab since the indication was considered to be new for denosumab and because it would bring a significant clinical benefit in comparison with existing therapies for this indication.