European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
PROLIA

International Nonproprietary Name (INN): ***denosumab***

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Prolia, 60mg/ml, solution for injection intended for osteoporosis and bone loss associated with hormone ablation.

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

The active substance of Prolia is denosumab, a drug affecting bone structure and mineralization medicinal product *(*ATC Code M05BX04*).* Denosumab is a human monoclonal antibody that targets and binds with high affinity and specificity to RANK ligand (RANKL), preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.

The benefits with Prolia are its ability to significantly reduce the risk of vertebral, hip and non-vertebral fractures and increase bone mineral density in postmenopausal women at increased risk of fractures. Prolia also significantly reduces the risk of vertebral fractures and increases bone mineral density in men with prostate cancer at increased risk of fractures receiving hormone ablation.

The most common side effects are urinary tract infection, upper respiratory tract infection, cataract, constipation, rash, sciatica and pain in extremity.

A pharmacovigilance plan for Prolia, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

- Treatment of osteoporosis in postmenopausal women at increased risk of fractures. Prolia significantly reduces the risk of vertebral, non vertebral and hip fractures.
- Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, Prolia significantly reduces the risk of vertebral fractures.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the Agency in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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