21 November 2013
EMA/CHMP/523516/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic Acid Accord

zoledronic acid

On 21 November 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zoledronic Acid Accord 4mg/5ml concentrate for solution for infusion intended for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone, and the treatment of tumour-induced hypercalcaemia (TIH).

The applicant for this medicinal product is *Accord Healthcare Limited*. 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 Zoledronic Acid Accord is zoledronic acid (as monohydrate), a bisphosphonate (M05BA08). Zoledronic acid stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases. Patients with tumours can have high levels of calcium in their blood, released from the bones. By preventing the breakdown of bones, zoledronic acid also helps to reduce the amount of calcium released into the blood.

Zoledronic Acid Accord is a generic of Zometa, which has been authorised in the EU since 20 March 2001. Studies have demonstrated the satisfactory quality of Zoledronic Acid Accord. This product is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Zometa was not required. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Zoledronic Acid Accord will be implemented as part of the marketing authorisation.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

The approved indication is:

- "Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone.
- The treatment of tumour-induced hypercalcaemia (TIH)".

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 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 Zoledronic Acid Accord and therefore recommends the granting of the marketing authorisation.