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Press Office

Press release

Novartis Europharm Ltd. withdraws its application for an extension of indication for Zometa (zoledronic acid)

The European Medicines Agency (EMA) has been formally notified by Novartis Europharm Ltd. of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Zometa (zoledronic acid) 4 mg powder and solvent for solution for infusion and 4 mg/ 5 ml concentrate for solution for infusion.

On 22 December 2009, Novartis Europharm Ltd. submitted an application to extend the marketing authorisation for Zometa to include the adjuvant treatment of hormone receptor-positive early breast cancer (EBC) in premenopausal women for whom hormonal therapy is recommended. At the time of withdrawal, the application was under review by the EMA's Committee for Medicinal Products for Human Use (CHMP).

Zometa was first authorised in the European Union on 20 March 2001. It is currently authorised for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone, as well as for the treatment of tumour-induced hypercalcaemia.

In its official letter, the company stated that its decision to withdraw the application was based on the CHMP's view that the data provided in support of the application so far would not allow the Committee to recommend approval.

Zometa continues to be authorised for the currently approved indications.

More information about Zometa and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMA website after the 17 – 20 January 2011 CHMP meeting.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

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2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

3. On 15 December 2007 Novartis Europharm Ltd. withdrew an application to extend the marketing authorisation for Zometa to include prevention of fracture and bone loss in postmenopausal women with early-stage breast cancer treated with aromatase inhibitors.

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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