European Medicines Agency
Press office

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PRESS RELEASE

Novartis withdraws its application to extend the marketing authorisation for Zometa

The European Medicines Agency (EMEA) has been formally notified by Novartis Pharma AG of its decision to withdraw the application to extend the marketing authorisation to include a new indication for the medicinal product Zometa (zoledronic acid).

Zometa was first authorised in the European Union in March 2001. It is currently authorised for 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.

On 20 December 2006, Novartis Pharma submitted an application to extend the currently authorised indications for Zometa to include prevention of fracture and bone loss in postmenopausal women with early-stage breast cancer treated with aromatase inhibitors. At the time of the withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of the application was based on the CHMP's consideration that the data provided did not allow them to recommend authorisation of the extension of indication.

Despite the company's decision to withdraw this application, Zometa continues to be available in the currently approved indications.

More information about Zometa and the state of the scientific assessment at the time of withdrawal of the new indication will be made available in a question-and-answer document that will be published on the EMEA website after the next meeting of the CHMP on 10-13 December 2007.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Zometa is available in the European Public Assessment Report (EPAR)
3. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel: (44-20) 74 18 84 27, E-mail: press@emea.europa.eu