NOVARTIS

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Dr. Eric Abadie
CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London, E14 4HB
United Kingdom

14 December 2010

Re: Withdrawal of Zometa (zoledronic acid) type II variation EMEA/H/C/336/II/034

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Novartis Europharm Limited has taken the decision to withdraw the application for a new indication for Zometa 4 mg powder and solvent for solution for infusion and Zometa 4 mg/5 ml concentrate for solution for infusion in "*adjuvant treatment of hormone receptor-positive early breast cancer (EBC) in premenopausal women for whom hormonal therapy is recommended*".

The withdrawal is based on the following reason:
The CHMP considers that the data provided in support of the proposed new indication so far do not allow the committee to conclude with a recommendation for approval of this type II variation application

This decision will not have consequences for patients enrolled in any ongoing Novartis sponsored Zometa clinical trial.

Following withdrawal, Novartis intends to further evaluate the available data and we reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA webpage.

Yours faithfully,

On behalf of Novartis Europharm Ltd

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Senior DRA Manager