[redacted]

Dr Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use
European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
London E14 5EU
UNITED KINGDOM

13th January 2017

Subject: Withdrawal of Procedure No. EMEA/H/C/002173/II/0045. Extension of Indication to include "Treatment of Hypercalcemia of Malignancy refractory to intravenous bisphosphonate".
XGEVA (denosumab) 120 mg solution for injection

Dear Dr Salmonson,

It is with regret that I write to inform you that, at this point in time, Amgen Europe BV has taken the decision to withdraw the application for a new indication for XGEVA in the Treatment of Hypercalcemia of Malignancy refractory to intravenous bisphosphonate.

This withdrawal is based on the following reason:

- The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk assessment for proposed indication as described above.

Amgen reserves the right to make further submissions at a future date in this or other therapeutic indications.

Amgen would like to sincerely thank the (Co) Rapporteurs, EMA, PRAC and the CHMP for their time dedicated to reviewing this application and the support provided during the review process.

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

Yours sincerely,

[redacted]

Amgen Europe BV

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