AMGEN

International Regulatory Affairs

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Dr Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use
European Medicines Agency (EMA)
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UNITED KINGDOM

17th October 2017

Subject: Withdrawal of KYOMARC (bevacizumab), 25 mg/mL concentrate for solution for infusion - EMEA/H/C/004360/0000.

Dear Dr Salmonson,

I would like to inform you that, at this point in time, Amgen Europe BV has taken the decision to withdraw the application for Marketing Authorisation of KYOMARC (bevacizumab) 25 mg/mL concentrate for solution for infusion, which was intended to be used for the treatment of cancer of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer, platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, and cancer of the cervix.

This withdrawal of the duplicate Marketing Authorisation Application of KYOMARC is due to marketing considerations.

At the time of this withdrawal, Amgen Europe BV has responded to the CHMP List of Outstanding Issues. Amgen Europe BV believes that the list of Outstanding Issues will be satisfactorily addressed by the responses submitted, and will continue with the Marketing Authorisation Application for MVASI (bevacizumab, product reference H0004728).

There are no consequences of the withdrawal and there are no ongoing clinical trials and compassionate use programmes.

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,