21 February 2018

Dr Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use

Dr. Martina Weise
CHMP Rapporteur (BfArM)

Dr. Koenraad Norga
CHMP Co-Rapporteur (famhp)

European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
London E14 5EU
UNITED KINGDOM

Subject: Withdrawal of Aranesp, (darbepoetin alfa), - Procedure No. EMEA/H/C/000332/II/0142. Extension of Indication to include "Treatment of anaemia in adult patients with low transfusion demand in low or intermediate-1-risk myelodysplastic syndromes".

Dear Dr Salmonson, Dr Weise and Dr. Norga,

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 Aranesp in the treatment of anaemia in adult patients with low transfusion demand in low or intermediate-1-risk myelodysplastic syndromes.

This withdrawal is based on the following reason:

- CHMP considers that the data provided in support of the new indication do not allow the committee to conclude with a recommendation for approval of this type II variation application

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.