[redacted]

Dr. T Salmonson
European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

19 January, 2015

Re: Rienso – EMEA/H/C/002215/II/0008 - Withdrawal of Type II variation for extension of the indication for a medicinal product already authorised

Dear Dr. Salmonson,

I would like to inform you that, at this point in time, Takeda Pharma A/S (the 'MAH') in conjunction with its licensing partner AMAG Pharmaceuticals, Inc., has taken the decision to withdraw the application to extend the indication for Rienso 30 mg/ml solution for infusion to adult patients with IDA from any underlying conditions (all-cause IDA).

The withdrawal is based on the Rapporteur Assessment report received by Takeda on 15 January 2015 which does not support approval in the broader, non-CKD patient population until additional confirmative clinical data become available.

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

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

Yours faithfully,

[redacted]