19th September 2008

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

Subject: Withdrawal of Ramelteon 4 & 8mg tablets MAA - **EMEA/H/C/000838//0000**

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Takeda Global Research & Development Centre (Europe) Ltd. have taken the decision to withdraw the application for the Marketing Authorisation of Ramelteon 4 & 8mg tablets, which was intended to be used for the treatment of primary insomnia.

This withdrawal is based on the company's current plan to consider seeking scientific advice, with a view to extending the clinical programme, which would address the CHMP's questions regarding the benefit risk profile.

Currently there are no ongoing trials with this product and there is not a compassionate use programme in the EU.

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 EMEA website.

Yours sincerely,