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21 March 2013

Dr. Tomas Salmonson
CHMP chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB

Cc: [redacted]

**Subject: Withdrawal of Raxone®, idebenone, 150 mg film-coated tablets**
**EMEA/H/C/002425**

Dear Dr Salmonson:

I would like to inform you that, at this point of time, Santhera Pharmaceuticals (Deutschland) has taken the decision to withdraw the application for Marketing Authorisation of Raxone, idebenone 150 mg film-coated tablets, which was intended to be used for the treatment of Leber's Hereditary Optic Neuropathy.

This withdrawal is based on the following reasons:

- *Other: strategic reasons*

New clinically meaningful data has emerged which provides further supporting evidence on clinical efficacy of idebenone in the treatment of LHON. We believe these data will adequately address the points raised by the CHMP in its adopted Opinion of 17 January 2013.

Notwithstanding availability of these new data and data analysis, we have been informed by the Secretariat of the European Medicines Agency and the Rapporteur and Co-Rapporteur who have been appointed by the CHMP to lead the re-examination procedure that such data and data analysis cannot be introduced into the detailed grounds for re-examination.

In the light of this guidance and given the importance of these data to corroborate the submitted clinical trial data contained in the original marketing authorisation application as supportive evidence on clinical

efficacy, we have therefore decided to withdraw this Centralised marketing authorisation application with an immediate effect.

There is no ongoing clinical trial with idebenone in LHON. Patients in compassionate use programme who are taking idebenone can continue treatment.

We wish to thank you and your staff for the helpful guidance provided during the course of the procedure.

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

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

Yours sincerely,

[redacted]
Senior Regulatory Affairs Manager

[redacted]
Chief Scientific Officer