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To Whom This May Concern:

In its continuing commitment to explore new treatment options for Friedreich's Ataxia and other orphan neuromuscular diseases, Santhera has been conducting clinical trials to evaluate its product CATENA<sup>®</sup>, a treatment currently available under conditional authorization in Canada to treat Friedreich's Ataxia. We recently received preliminary results of the CATENA US Phase III clinical trial, IONIA (Idebenone effects On Neurological ICARS Assessments), which evaluated the change in the International Cooperative Ataxia Rating Scale (ICARS), a neurological scale.

The top-line results from the IONIA study show that the primary endpoint (improvement on the ICARS) did not reach statistical significance. In regards to safety of CATENA, no new safety or tolerability signals were seen.

In this six month 70 patient study, the active treatment arms showed consistently lower ICARS (a higher ICARS score indicates greater severity of neurological impairment) scores compared to baseline and placebo, as seen in prior studies. Our initial impressions of the data indicate that due to a lower-than-expected effect size combined with the surprising results in the placebo group showing improvement in key parameters rather than the typical deterioration seen both in previous studies and in the natural history of the disease, the difference between idebenone treated patients and placebo treated patients did not reach statistical significance. We are conducting a full analysis of the data to determine the basis of this unusual outcome.

In the meantime, we look forward to the results of our ongoing European Phase III trial (MICONOS), which is both a longer study (12 months) and has enrolled a significantly larger group of patients (232). We expect those data to be available in early 2010.

CATENA has a conditional marketing authorization granted by Health Canada based on a phase II trial. This conditional marketing authorization has allowed patients access to CATENA while awaiting the results of a confirmatory study.

The results of the study will be reviewed with Health Canada in order to determine the best way forward. In the meantime, CATENA will continue to be available to patients already taking it and to

those who obtain new prescriptions for CATENA. Patients receiving new prescriptions for CATENA should call our CATENA Support Program at 866-270-1733 with questions regarding obtaining CATENA and for reimbursement assistance.

We will continue to be in contact with you as new information becomes available. In the meantime, if you have any questions related to CATENA, feel free to contact me.

Sincerely,

A handwritten signature in dark ink, reading "William T. Andrews". The signature is written in a cursive style with a long horizontal flourish extending to the right.

William T. Andrews, MD, FACP  
Vice President, Medical Affairs