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## **CHMP Confirms Original Opinion on Santhera's SNT-MC17/ Idebenone for Treatment of Friedreich's Ataxia**

**Liestal, Switzerland, November 19, 2008 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announced today that the European Medicines Agency (EMA) has informally advised that it would maintain its negative opinion on the Company's Marketing Authorization Application (MAA) for SNT-MC17/idebenone in Friedreich's Ataxia. According to the information received, the Committee for Medicinal Products for Human Use (CHMP) of the EMA in its reexamination concluded that it cannot support an early approval at this point in time but rather prefers to wait until additional data from at least one of Santhera's two pivotal trials become available for review. The Company has two Phase III studies running and both these trials have achieved their recruitment target. Santhera intends to file for marketing authorization in the United States and in the European Union next year.**

Klaus Schollmeier, Chief Executive Officer of Santhera, commented: "Our success in making additional data available in the near future has been the major obstacle throughout the regular review process as well as the reexamination. The confirmation of the original CHMP opinion is obviously a disappointment but not a surprise. As a result of today's decision, Friedreich's Ataxia patients in the European Union must continue to wait for the first controlled pharmaceutical product to treat their devastating disease. We confirm our commitment to make this important drug available to patients in Europe and in the United States as we are already able to do in Canada."

Meanwhile, Santhera's two Phase III trials are both recruited. In Europe, the twelve-month MICONOS (Mitochondrial Protection With Idebenone In Cardiac Or Neurological Outcome Study) trial has achieved the enrollment of 204 Friedreich's Ataxia patients and will be closed to recruitment shortly. In the United States, the last patient was randomized into the IONIA (Idebenone effects On Neurological ICARS Assessments) trial on October 31, 2008. A total of 70 Friedreich's Ataxia patients have been enrolled into this six-month study. Subject to positive outcome of the IONIA trial, Santhera expects to file a New Drug Application with the US Food and Drug Administration (FDA) before the end of 2009. In the United States, the program has been granted fast track status by the FDA in 2007. A new MAA is planned to be submitted to the EMA within the same timeframe.

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**About Santhera**

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the discovery, development and commercialization of small-molecule pharmaceutical products for the treatment of severe neuromuscular diseases, an area of high unmet medical need which includes many orphan indications with no current therapy. Santhera currently investigates three compounds in five clinical-stage development programs. The Company's first product, SNT-MC17 (INN: idebenone), has received a marketing approval with conditions from Health Canada to treat Friedreich's Ataxia and is marketed under its brand name CATENA®. The product is also under review in Switzerland, while two pivotal clinical trials in the United States and in Europe have recently achieved their enrollment targets. The compound has also shown efficacy in a phase II clinical trial as a potential treatment for Duchenne Muscular Dystrophy. For further information, please visit the Company's website [www.santhera.com](http://www.santhera.com).

*CATENA® is a trademark of Santhera Pharmaceuticals, registered in Canada and the United States.*

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