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Santhera Enrolls Last Patient in European Phase III Trial Evaluating SNT-MC17/Idebenone in Friedreich's Ataxia

Liestal, Switzerland, December 11, 2008 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today that recruitment has been completed for its 12-month European Phase III trial evaluating SNT-MC17/idebenone in Friedreich's Ataxia, a severe and degenerative neuromuscular disorder. The 13 study centers in six European countries have enrolled a total of 232 adult patients. The completion of recruitment in Europe follows shortly after Santhera announced a similar milestone for its six-month pivotal Phase III trial in the United States in the same indication. SNT-MC17/idebenone is approved by Health Canada for treatment of Friedreich's Ataxia and available under the brand name CATENA®.

The European Phase III trial named MICONOS (Mitochondrial Protection with Idebenone In Cardiac Or Neurological Outcome Study) is a double-blind, randomized, placebo-controlled study of 12 months duration investigating the efficacy of three doses of SNT-MC17/idebenone compared to placebo. The primary endpoint is the change in the International Cooperative Ataxia Rating Scale (ICARS), a neurological scale, where the difference between baseline and end of treatment for each of the dosing groups will be compared with the change in the placebo group. The MICONOS study also investigates cardiac outcomes and additional neurological endpoints as well as activities of daily living parameters. As of today, more than 100 patients have completed the trial and have been enrolled into an open label extension study at the highest dose level.

"In Canada, the same drug, known by the brand name CATENA®, was made commercially available in October and initial demand has exceeded our expectations. The strong demand underlines the high unmet medical need in Friedreich's Ataxia and patients' rapid adoption of the first approved therapy for this disease," said Klaus Schollmeier, Chief Executive Officer of Santhera. "By completing enrollment of the European Phase III trial, we have achieved another important milestone in the development of SNT-MC17/idebenone for Friedreich's Ataxia. With a mostly adult population, this trial will help us to understand how these patients can derive the maximum benefit from the drug."

The MICONOS trial is Santhera's second Phase III trial in Friedreich's Ataxia which is now fully enrolled. Recently the Company announced that its IONIA (Idebenone effects On Neurological ICARS Assessments), trial has enrolled 70 patients in the United States. Whilst the MICONOS study investigates the efficacy of SNT-MC17/idebenone primarily in adult patients for a 12-month treatment period, the IONIA study assesses the efficacy and safety of the drug in 8 to 17 year old

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patients for six months. Santhera expects that the IONIA data will provide the basis of a New Drug Application filing in the United States and a Marketing Authorization Application filing in the European Union before the end of 2009. The MICONOS study is expected to provide supplementary data to support additional labeling in 2010.

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About Friedreich's Ataxia

Friedreich's Ataxia is a rare but severe genetic neuromuscular disorder that results in the degeneration of an individual's nervous tissue leading to uncoordinated movements, loss of muscle control, loss of ambulation and thickening of the walls of the heart which frequently leads to a shortened life span. Friedreich's Ataxia affects both Caucasian males and females equally and it is estimated that a total of about 20,000 patients suffer from the disease in North America and Europe. Average life expectancy for Friedreich's Ataxia patients is limited to approximately 35 to 50 years.

The disorder results from an inherited defect in the gene encoding for *frataxin*. Reduced levels of this protein ultimately result in impaired energy production in mitochondria, the cells' energy production centers, and elevated oxidative stress. Tissues that have the highest need for energy, in particular nerve and cardiac tissues, are primarily affected by *frataxin* deficiency resulting in loss of nerve cells and pathological changes in heart muscle anatomy and function.

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 has three compounds in five clinical-stage development programs. The Company's first product, SNT-MC17/idebenone, has received a marketing approval with conditions from Health Canada to treat Friedreich's Ataxia where it is marketed by Santhera under its brand name CATENA®. The product is also under review in Switzerland for this indication, whilst two pivotal clinical trials in the United States and in Europe respectively, 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.

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

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