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Santhera's Ongoing Studies Prevent CHMP Review under Small Patient Populations Guideline

Company Expects Negative CHMP Opinion on MAA for SNT-MC17/Idebenone in Friedreich's Ataxia

Liestal, Switzerland, July 24, 2008 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has informally advised Santhera that it would not support a positive opinion for the Marketing Authorization Application (MAA) for SNT-MC17/idebenone to treat patients with Friedreich's Ataxia at this time. According to the information received, Santhera's ongoing phase III trials prevented the CHMP from reviewing the Company's application under the EMA Guideline on Clinical Trials in Small Populations as requested by Santhera in its MAA filing. The Company's understanding is that the Committee believes it cannot approve the drug before data from at least one of Santhera's advanced phase III clinical programs in Europe and the United States are submitted for review.

In clinical studies submitted to the CHMP as part of the approval process, SNT-MC17/idebenone showed statistically and clinically relevant improvements in Friedreich's Ataxia patients, as measured by Activities of Daily Living scores as well as in cardiac and neurological functions. The CHMP Joint Assessment Report supports the safety profile, preclinical data and technical development of SNT-MC17/idebenone as sufficient to potentially meet its criteria for approval. However, the CHMP concluded that Santhera had not submitted a sufficient set of data demonstrating a clear positive risk/benefit balance for approval under the Committee's standard clinical review guidelines. The MAA filing was based primarily on positive pediatric data generated in the NICOSIA (NIH Collaboration with Santhera in Ataxia) study, a collaborative trial with the US National Institutes of Health, analyzing a variety of neurological and cardiac outcome measures and was supported by evidence from several academic trials in a wider population that demonstrated efficacy in the treatment of cardiac hypertrophy in Friedreich's Ataxia patients.

Klaus Schollmeier, Chief Executive Officer of Santhera, commented: "The possible negative CHMP opinion is obviously disappointing and surprising as well. Based on earlier discussions, we had expected to qualify for the EMA Guideline on Clinical Trials in Small Populations. When we submitted the MAA, our European phase III clinical trial MICONOS was running, but we were very concerned about our enrollment prospects. At that time, our US phase III trial IONIA had not even yet started. We kept the Committee informed about the status of both trials throughout the MAA filing process. It seems that our success in gathering additional data has been working against us. Together with our partner Takeda, we will evaluate our options for making SNT-MC17/idebenone available as a controlled pharmaceutical product to Friedreich's Ataxia patients in Europe as soon as feasible".

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The EMEA has a formal process whereby the MAA sponsor may request reexamination of the CHMP's initial negative opinion, including a review of the dossier by an independent specialist Scientific Advisory Group. If Santhera requests such a review, a final opinion could be rendered within approximately six months. Santhera together with its marketing partner Takeda are evaluating this option carefully. If this alternative is pursued, the appeal must be submitted within the next 15 days from the official CHMP opinion.

Update on ongoing Phase III clinical trials

In Europe, the MICONOS (Mitochondrial Protection With Idebenone In Cardiological Or Neurological Outcome Study) phase III trial has currently enrolled approximately 90% of the patients needed to complete recruitment and is on track for full enrollment by the end of 2008.

In the United States, the IONIA (Idebenone effects On Neurological ICARS Assessments) phase III trial has currently enrolled 41 patients. It was agreed with the US Food and Drug Administration under a Special Protocol Assessment process to recruit a minimum of 51 patients but to include more patients if available. Given the current prospects for patient availability, Santhera and its US clinical investigators believe that the final study will include about 60 to 65 patients.

Pipeline Status and Updated Financial Guidance

Santhera will provide information on the status of its entire development pipeline and to update on financial guidance as part of its Half-Year Financial Results Report on August, 22, 2008.

Conference call

At **19.00 CET / 18.00 UKT / 13.00 EST** on **July 24, 2008**, Santhera will host a conference call. People interested in participating may join the teleconference facility using the following dial-in in **Switzerland +41 52 267 07 36**. The conference call will be recorded for playback and is available one hour after the conference call ends and for 20 days under +41 52 267 07 00 (reference no. 668713).

The Company was informed by the CHMP at 18:36 CET and acknowledges the late-breaking nature of this news. Management will be available after the call as well as all day Friday to respond to questions from anyone who missed the opportunity to participate in the live teleconference conference.

About Friedreich's Ataxia

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

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The disorder results from a genetic 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 pathological changes in heart muscle anatomy and function and loss of nerve cells.

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About Santhera

Santhera Pharmaceuticals (SWX: SANN) is a Swiss specialty pharmaceutical company focused on the discovery, development and marketing 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 will be marketed under its brand name Catena[®]. The product is also under review by health authorities in the EU and in Switzerland, while in the United States, a pivotal phase III trial is recruiting patients. SNT-MC17/idebenone has also shown efficacy in a phase II clinical trial as a potential treatment for the indication Duchenne Muscular Dystrophy. For further information, please visit www.santhera.com.

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