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Santhera Receives First Product Approval: Health Canada Approves Catena[®] for Treatment of Friedreich's Ataxia

Liestal, Switzerland, July 24, 2008 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announced today that Health Canada has approved with conditions SNT-MC17/idebenone for the treatment of Friedreich's Ataxia. Health Canada's decision is the first marketing authorization worldwide for any Friedreich's Ataxia therapy. The new drug will be marketed in Canada under the brand name Catena[®]. Santhera has established a wholly owned Canadian subsidiary, Santhera Pharmaceuticals (Canada), Inc. recently incorporated in Montréal, Quebec, to address the needs of Canada's several hundred patients with this rare and severely progressive muscle disease. Launch of Catena is anticipated for the end of October 2008.

In clinical studies submitted to Health Canada as part of the approval process, Catena showed statistically and clinically relevant improvements in Friedreich's Ataxia patients, as measured by Activities of Daily Living scores as well as cardiac and neurological functions. The approved product labeling allows for the treatment of symptoms of Friedreich's Ataxia. Two doses are approved: a starting dose of 450 mg/day for patients below 45 kg body weight and 900 mg/day for patients above 45 kg body weight whereby treating physicians have an option to dose up to 1,350 mg/day for patients below 45 kg body weight and up to 2,250 mg/day for patients of more than 45 kg body weight if needed. Under the conditions of the Notice of Compliance with Conditions, Santhera has agreed to submit additional data from its ongoing phase III clinical trial in the United States to confirm the efficacy of the therapy.

Klaus Schollmeier, Chief Executive Officer of Santhera said: "We are very pleased about this market authorization by the Canadian authority. Health Canada concluded that the data presented were promising enough to allow Catena's approval for the benefit of patients now while requiring confirmatory efficacy data when they become available. Today's approval is a major milestone for the Friedreich's Ataxia community in Canada and elsewhere. For the first time, physicians will be able to offer patients an approved, safe and efficacious therapy to treat their devastating disease." He continued: "This first marketing authorization marks a significant event for our Company, one that has been our goal since the inception of Santhera in 2004. Today, Santhera's vision of offering therapies for orphan indications is becoming reality. The entire team at Santhera is energized by this success and is even further encouraged to work towards approvals in other regions."

MJ Roach, VP Marketing & Sales and Santhera's General Manager for North America, commented: "Canada's marketing authorization provides an excellent foundation to establish a medical and marketing platform in North America for the treatment of rare neuromuscular diseases in general

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and for Friedreich's Ataxia in particular. The Canadian market will also provide valuable insights for launching the product in the United States, once the ongoing clinical trial is completed and the product is approved. We look forward to working with physicians in Canada who prescribe Catena to Friedreich's Ataxia patients."

Update on ongoing phase III clinical trial

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.

Conference call

At **19.00 CET / 18.00 UKT / 13.00 EST** on **July 24, 2008**, Santhera will host a conference call. Anyone 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).

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.

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.

About Catena[®]

Catena may be useful in the symptomatic management of patients with Friedreich's Ataxia. The drug is believed to increase the supply of energy to cells in the body. Additionally it has antioxidant properties and may protect the cells in the body which are damaged by the disease.

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

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About Notice of Compliance with Conditions

A Notice of Compliance with Conditions (NOC/c) is an authorization to market a drug in Canada issued by Health Canada, indicating that the sponsor has agreed to undertake additional studies to confirm the clinical benefit of the product. A market authorization under the NOC/c policy allows Health Canada to provide earlier market access to potentially life-saving drugs. Eligibility for an NOC/c is restricted to promising new drug therapies intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions for which a) there is no alternative therapy available on the Canadian market or, b) where the new product represents a significant improvement in the benefit/risk profile over existing products. Once a sponsor provides satisfactory evidence of the drug's clinical effectiveness, and all the conditions agreed upon have been met, Health Canada will remove the conditions associated with market authorization in favor of a full approval.

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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 for the same indication, 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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Disclaimer/Forward-looking statements

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