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Santhera to Seek Canadian Market Approval for SNT-MC17 in Friedreich's Ataxia

Liestal, Switzerland, September 21, 2007 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announces today that, with the recent positive decision from Health Canada on eligibility, the Company will file a New Drug Submission (NDS) for SNT-MC17 (INN: idebenone) for the treatment of Friedreich's Ataxia (FRDA). The compound has shown clinical efficacy in FRDA patients on neurological as well as cardiac endpoints in several clinical studies and proved to be well tolerated in all studies so far. The Canadian decision follows shortly after the European Medicines Agency (EMA) accepted Santhera's filing of a Marketing Authorization Application (MAA) for SNT-MC17 in FRDA.

Following a recent meeting with the Therapeutic Products Directorate (TPD) of Health Canada and after the receipt of the positive decision on eligibility, Santhera now has 60 days to submit the NDS to the Canadian regulatory authorities. In response to TPD's decision, Santhera will file an application for a Notice of Compliance with Conditions (NOC/c). Health Canada's standard review process calls for a 235 day review target including 35 days for processing and screening. If the review is positive, the TPD will issue a Qualifying Notice for the NOC/c application which indicates that the product is eligible for market approval, subject to certain conditions, which must be agreed upon with TPD at a later point in time.

Based on extrapolated published epidemiology data, there is an estimate of several hundred FRDA patients in Canada. Upon approval, Santhera will market the product by its own. The Company has been granted an exclusive license to a use patent application for Canada filed by INSERM (Institut National de la Santé et Recherche Médicale) for the use of idebenone in FRDA.

Klaus Schollmeier, Santhera's CEO commenting on today's announcement said: "We are excited about Health Canada's decision. We will seek Canadian market approval with a safety and efficacy package that is equivalent to the file currently under review at the EMA. If everything goes according to plan, we may be able to launch SNT-MC17 in the Canadian market in late 2008, thus providing FRDA patients with the first approved pharmaceutical product for the treatment of this devastating disease."

About Friedreich's Ataxia (FRDA)

Friedreich's Ataxia (FRDA) 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. FRDA 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 FRDA 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. SNT-MC17 is believed to improve the balance and flow of electrons within the mitochondria, therefore increasing the energy production within nerve and muscle cells of FRDA patients, protecting these cells from cell death. A number of clinical trials have provided strong evidence that SNT-MC17 may offer an effective treatment option for FRDA associated heart wall thickening (cardiomyopathy). In addition, data from the collaborative NIH clinical trial suggest positive effects on neurological function.

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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. Santhera's vision is to become a leading specialty pharmaceutical company offering therapies for a number of indications in this area of high unmet medical need which includes many orphan indications with no current therapy.

Santhera currently has five clinical-stage development programs, three of which are investigating its lead compound, SNT-MC17 (INN: idebenone), for the treatment of Friedreich's Ataxia (FRDA), Duchenne Muscular Dystrophy (DMD) and Leber's Hereditary Optic Neuropathy (LHON). Another clinical program is investigating JP-1730 (INN: fipamezole) for the treatment of Dyskinesia in Parkinson's Disease (DPD) in cooperation with Juvantia, the compound's owner. The fifth program comprises SNT-317 (INN: omigapil) in Congenital Muscular Dystrophies (CMD), a compound in-licensed from Novartis. For the most advanced program, SNT-MC17 in FRDA, the Company has applied for marketing authorization in Europe and Canada. The compound is also in Phase III clinical development for FRDA in the US while the other clinical programs are in Phase II. For further information, please visit www.santhera.com.

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