



Press Release

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Santhera starts European Phase III Study with its Lead Compound *SNT-MC17 (idebenone) in Friedreich's Ataxia*

Liestal, Switzerland, December 15, 2005 -- Santhera Pharmaceuticals AG ("Santhera"), a Swiss-based biopharmaceutical company focused on neuromuscular diseases, announced today that it has started a European Phase III clinical study with its lead product SNT-MC17 (idebenone) in Friedreich's Ataxia (FRDA). The design of this study reflects the company's discussions with EMEA which took place earlier this year and will evaluate both the cardiac and neurological benefits of SNT-MC17 (idebenone).

The Phase III trial with SNT-MC17 (idebenone) is a double-blind, randomised, placebo-controlled study to determine its efficacy, safety and tolerability in the treatment of Friedreich's Ataxia patients with hypertrophic cardiomyopathy. The study will be performed in Germany, the UK and the Netherlands with possible extension to other EU territories. It will involve approximately 10 study centers and about 200 patients are expected to be enrolled. Patients will receive SNT-MC17 (idebenone) for a period of one year. Recruitment of patients into the trial has already started.

The Phase III study will compare the efficacy of three different doses of SNT-MC17 (idebenone) with placebo on the left ventricular mass index of FRDA patients. Hypertrophic cardiomyopathy, as measured by increased left ventricular mass indices is a prominent factor in both the morbidity and mortality of FRDA patients. In parallel this study will assess the efficacy of SNT-MC17 (idebenone) on the neurological symptoms of FRDA. This will be determined by measuring the changes in the International Cooperative Ataxia Rating Scale (ICARS).

In addition to the Phase III study, Santhera has an on-going collaboration with the National Institute of Health in the USA for FRDA and plans to initiate its own Phase III studies in the US next year for this indication with SNT-MC17 (idebenone). Santhera is also currently running a Phase IIa study in Belgium investigating the efficacy of SNT-MC17 (idebenone) for an additional neuromuscular disease indication, Duchenne Muscular Dystrophy.

Earlier this year, Santhera concluded a development and marketing agreement with Takeda Pharmaceuticals for SNT-MC17 (idebenone) in Friedreich's Ataxia. Under the terms of this agreement Takeda will support the overall clinical development of SNT-MC17 (idebenone) in FRDA and, upon approval, will be responsible for marketing the drug for this indication Friedreich's Ataxia in all EU countries and Switzerland. Santhera will be fully responsible for development, registration and supply of the product. Santhera continues to own the rights to the product outside the EU and plans to market the product in the US under its own name. Santhera also retains all rights to other potential indications for SNT-MC17 (idebenone) such as Duchenne Muscular Dystrophy.

Thomas Meier, Ph.D., Chief Scientific Officer of Santhera commented: "SNT-MC17 (idebenone) is the first compound with a clear beneficial pharmacological profile in FRDA and therefore has the potential to become the first-line treatment for Friedreich's Ataxia, a

disease for which there is currently no effective treatment or cure available. The protocol of our Phase III trial takes into account our discussions with the EMEA earlier this year. We are very pleased to collaborate in this study with numerous distinguished physicians and clinical experts who have in the past already contributed to the understanding of the FRDA-pathology.”

Klaus Schollmeier, Ph.D., Chief Executive Officer of Santhera declared: “The start of the first Phase III trial with our lead compound SNT-MC17 is a key milestone in the development of Santhera Pharmaceuticals. Based on the growing pool of positive data supporting the product’s use in FRDA and the strong commitment of our partners including Takeda, the NIH, and patient organizations in the US and Europe we are confident that we will soon be in a position to help FRDA patients suffering from this devastating disease.”

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About Friedreich’s Ataxia (FRDA)

Friedreich’s Ataxia is a disabling neuromuscular disease that ultimately leads to death. The disease is inherited and causes progressive damage to the nervous system causing symptoms including muscle weakness, speech problems and heart disease. Symptoms usually appear between the ages of 10 and 30 years of age. Generally, within 15 to 20 years of the first symptoms appearing, the patient is confined to a wheelchair and in later stages becomes completely incapacitated. Most patients die in early to mid adulthood, and heart disease is the most common cause of death. The disorder results from a genetic defect in the Frataxin gene that results in oxidative stress in the mitochondria. The disease affects primarily the Caucasian population, where the incidence rate is approximately 1 in 30,000 to 50,000. It affects some 10,000 patients in the US and 10,000 patients in Europe.

About Santhera

Santhera Pharmaceuticals AG is a Swiss biopharmaceutical company focused on the discovery, development and marketing of small molecule pharmaceutical products for the treatment of neuromuscular diseases. The company’s lead product, SNT-MC17 (idebenone) is in a n European Phase III for the treatment of Friedreich’s Ataxia, a rare but devastating disease which is ultimately fatal. Santhera has orphan drug designation for this indication in both the US and EU. The Company intends to market the product in the US, and has exclusively licensed to Takeda rights to market the product for FRDA in Europe. SNT-MC17 (idebenone) is also in a Phase II trial for Duchenne Muscular Dystrophy. Santhera has developed a pipeline of preclinical drug candidates which it will progress in neuromuscular diseases and out license in areas outside its core therapeutic focus. Santhera’s program on novel DPP IV inhibitors for the treatment of metabolic diseases, including Type II diabetes is licensed to Biovitrum (Sweden).

Santhera was formed in 2004 through the merger of MyoContract AG and Graffinity Pharmaceuticals AG providing it with a fully integrated platform for the discovery and development of drug candidates. The Company has operations in Basel, Switzerland and Heidelberg, Germany. Santhera has attracted investment from leading global industry investors including Merlin Biosciences Limited, Oxford Bioscience Partners, NGN Capital, 3i Group plc, Carnegie Asset Management, The Novartis Venture Fund, Varuma AG, GIMV, Heidelberg Innovation, Altana Innovationsfonds, Clariden Bank, The Dow Chemical Company, TechnoStart, tbg, the Swiss Foundation for Research on Muscle Diseases, and private investors.

For further information, please visit www.santhera.com.

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