



Press Release

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Santhera and the NIH Collaborate to Evaluate SNT-MC17 in Friedreich's Ataxia

Liestal, Switzerland – November 3rd, 2005 -- Santhera Pharmaceuticals AG ("Santhera") of Switzerland announced today the start of a collaborative clinical trial with the US National Institutes of Neurological Disorders and Stroke (NINDS) at the National Institute of Health (NIH) to evaluate SNT-MC17 (idebenone) in patients affected by Friedreich's ataxia (FRDA), a devastating life-threatening neuromuscular disease.

This phase II study is designed to provide data on the safety and efficacy of SNT-MC17 in FRDA patients at various doses. These results will supplement previous clinical work which suggested that the product is efficacious in treating the cardiac complications that are the main cause of death in FRDA patients.

Under the collaboration the NIH will conduct the clinical trial, which is expected to enroll 48 patients with FRDA and last six months. Santhera will supply the drug material to be tested and contribute to the data management and analysis as well as regulatory support. The primary endpoint of the study is the reduction of oxidative stress markers. Importantly, this study also aims to analyze changes in several neurological and functional parameters as a result of treatment with SNT-MC17. These parameters will be secondary endpoints of the study. Data obtained from this study will be used as part of the development program for SNT-MC17 (idebenone) both in the US and in Europe; Santhera plans to start a pivotal Phase III trial in Europe later this year.

Nicolas Di Prospero MD, who is the principal investigator at NINDS, declared: "Friedreich's ataxia is a life-threatening disease for which no effective treatment is approved. Previous studies have suggested that idebenone can slow or arrest the development of hypertrophic cardiomyopathy and may also have beneficial effects on disease-specific neurological symptoms. By conducting this study, we hope to get an indication of whether neurological benefits are conferred by idebenone/SNT-MC17 in FRDA patients."

Mr. Ron Bartek, President of the Friedreich's Ataxia Research Alliance (FARA), the patient organization in the US dedicated to supporting efforts to find treatments for FRDA concluded: "We are pleased that Santhera and the scientists at NINDS have teamed up to accelerate the clinical development and finally approval of SNT-MC17 (idebenone) which is currently the only pharmacological treatment option with clear proof of concept in clinical trials."

Thomas Meier, Ph.D., Santhera's Chief Scientific Officer commented: "We are very pleased to be collaborating with Dr. Di Prospero and his colleagues at the NIH, who have experience with this drug from previous Phase I trials. In this new trial, we will evaluate the neurological impact of our lead compound SNT-MC17 (idebenone); this is an important additional step in determining its full benefit to FRDA patients. Independently, we will enroll our Phase III clinical program in Europe and will subsequently commence a Phase III study in the US."

Ends

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 FARA

The Friedreich's Ataxia Research Alliance (FARA) is a national, public, 501(c)(3), non-profit, tax-exempt organization dedicated to the pursuit of scientific research leading to treatments and a cure for Friedreich's ataxia. FARA's mission is to slow, stop, and reverse the damage caused by this disorder. <http://www.FARResearchAlliance.org>

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 about to enter 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 in Europe. 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.

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