Santhera Reports Encouraging, First Data from Phase IIa Clinical Trial with SNT-MC17 in Duchenne Muscular Dystrophy

Liestal, Switzerland, October 29, 2007 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announces today positive, first results from a 12 month Phase IIa clinical trial with SNT-MC17 (INN: idebenone) in Duchenne Muscular Dystrophy (DMD) as measured by cardiac and respiratory parameters. Santhera therefore is committed to further clinical development of SNT-MC17 in DMD.

This exploratory Phase IIa trial was a 12-month double-blind, randomized, placebo-controlled study conducted at the University of Leuven, Belgium. In total 21 DMD patients between the age of 8 and 16 years were enrolled to assess the efficacy and tolerability of one dose level of SNT-MC17 (450 mg/day) compared to placebo. Thirteen patients were receiving SNT-MC17 while 8 patients were randomized to the placebo group. There were no drop-outs in the study and the compliance was very good. Importantly, there was no difference in the safety and tolerability of SNT-MC17 compared to placebo underlining again the excellent safety profile of SNT-MC17 also in this pediatric population.

The primary objective was to assess whether SNT-MC17 improves or slows the decline in cardiac function in DMD patients, applying a comprehensive echocardiographic approach that included cardiac tissue Doppler and strain rate imaging technology. The primary endpoint was an assessment of the change in contractility of the region of the heart muscle that is affected early and most severely in DMD patients, measured by the peak systolic radial strain of the left ventricular inferolateral wall. After treatment for twelve months with SNT-MC17, DMD patients showed a trend to improve on this functional cardiac parameter compared to placebo ($P=0.098$).

In addition to these data, patients on SNT-MC17 improved also on certain respiratory parameters. Most striking and statistically significant was the improvement of DMD patients’ lung function measured by peak flow ($P=0.042$). Patients treated with SNT-MC17 ameliorated on this parameter, while patients on placebo deteriorated over the study period.

These findings are even more interesting as the majority of the older and more affected patients happened to be randomized to the SNT-MC17 treatment arm while the majority of the younger, less affected patients were randomized to the placebo arm. Although this led to differences in baseline which complicate interpretation of some of the findings, it is encouraging that even patients more severely affected appeared to show improvements.
“Despite the small sample size of this pilot study and the resulting limitations, we saw several interesting efficacy trends with SNT-MC17 that encourage further investigation of the drug in DMD. Particularly encouraging are changes in cardiac and more so respiratory parameters, as these represent life threatening complications of this disease. We would like to thank the patients and their parents who participated in this long-term randomized controlled pilot trial allowing us to test for the first time whether SNT-MC17 and its unique mode of action could potentially provide a therapeutic benefit for this devastating disease”, said Gunnar Buyse, associate professor of child neurology at the University of Leuven and principal investigator of the study.

“We were very fortunate for the opportunity in collaborating with the group in Leuven for this study. This team has great clinical and research experience in the neurological and cardiological assessment of DMD patients. Based on the promising data the study team has been able to analyze so far, we at Santhera are excited to proceed with the clinical development of SNT-MC17 for DMD. In the forthcoming weeks, the study team will further analyze the data and we expect that the findings will provide important guidance for the planning and execution of the subsequent clinical development”, added Thomas Meier, Chief Scientific Officer of Santhera.

The scientific rationale for this trial was based on promising data obtained in a collaborative study between the University of Leuven and Santhera. In a well established mouse model for DMD, it was demonstrated that early initiated and long-term administration of SNT-MC17 showed cardioprotective efficacy and improved exercise performance. These data were presented at the Annual Meeting of the American Academy of Neurology in Boston, USA, earlier this year.

Following further analyses of the data obtained in the Phase Ila trial reported today, Santhera intends to seek protocol advice from the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) in preparation of the further clinical development of SNT-MC17. The compound has already been granted orphan drug designation in DMD in both the EU and the US. In August 2007, Santhera and Takeda Pharmaceutical Company Limited (TSE:4502) announced an agreement under which Santhera granted exclusive marketing rights for SNT-MC17 in DMD in the EU and in Switzerland to Takeda.

About Duchenne Muscular Dystrophy (DMD)

DMD is the most common and a devastating type of muscular degeneration and results in rapidly progressive muscle weakness. It is a genetic, degenerative disease that is inherited in an X-linked recessive mode. DMD affects approximately 30,000 patients in the USA, EU, and Japan and its incidence is approximately 1 in 3,500 live born males. Women can be carriers of DMD but usually exhibit no symptoms. DMD is characterized by a complete loss of the protein dystrophin, leading to progressive muscle weakness and wasting through a complex cascade that involves impaired calcium homeostasis and oxidative stress. The average age of onset is between 3 and 5 years of age with a loss of ambulation in teenage patients. Dilated cardiomyopathy and respiratory failure are commonly associated with this chronic disease leading to early morbidity and mortality in DMD patients, frequently in late teens – early twenties.

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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 will be submitted shortly in 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.

Conference call

At 15.00 CET / 14.00 UKT / 09:00 EST today October 29, 2007, 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 (PIN code 274915). The conference call will be recorded for playback and is available one hour after the conference call ends and for 5 days under +41 52 267 07 00 (reference 559357#).

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