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Santhera Updates Development Strategy for SNT-MC17/idebenone in Friedreich's Ataxia in the US

Revised Clinical and Regulatory Strategy Based on Discussions with FDA Potentially Allows for Accelerated Development Timelines

Liestal, Switzerland, January 31, 2007 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, announces today a revised clinical and regulatory strategy aimed at accelerating the development timelines for its lead compound SNT-MC17/idebenone in Friedreich's Ataxia (FRDA) in the US. These changes are the result of discussions with the FDA (US Food and Drug Administration) following the positive results of the Company's collaborative clinical trial with the US National Institutes of Health (NIH). It is anticipated that both the number of patients needed for the Phase III clinical study and the trial's duration could be significantly reduced, thereby shortening the development timelines approximately by half a year as compared to the Company's previous plans.

The positive results of the clinical study conducted in collaboration with the NIH were presented at the 3rd International Friedreich's Ataxia Scientific Conference in Bethesda, Maryland, from November 10 to 12, 2006. Specifically, this trial showed improvement of neurological parameters and activities of daily living scores with intermediate and high doses of SNT-MC17/idebenone after six months of treatment in young FRDA patients. Santhera submitted these data to the FDA in late 2006. In a recent meeting with the Agency, the Company discussed potential amendments to its US clinical development plans for SNT-MC17/idebenone based on these new data. As a result of this meeting, Santhera will file a new protocol under its open IND (Investigational New Drug) within the next few weeks.

According to this protocol, the number of patients involved in the pending Phase III trial will be reduced substantially while the treatment period with SNT-MC17/idebenone will be considerably shortened. The protocol will reflect the major findings from the collaborative clinical trial with the NIH regarding neurological endpoints and the efficacy seen with the intermediate and high dose of SNT-MC17/idebenone. Upon filing the new protocol, Santhera will ask, as recommended by the FDA, for Special Protocol Assessment (SPA) with the Agency which is expected to occur within the next three months. Based on this schedule of events, patient recruitment is expected to start in summer 2007.

In the recent meeting, the FDA also confirmed that SNT-MC17/idebenone should be eligible for the Fast Track approval process that allows the agency to review a product's NDA (New Drug Application) with a higher priority and in a shorter time frame.

Klaus Schollmeier, Santhera's CEO commenting on today's announcement said: "I am pleased that the clinical trial in collaboration with the NIH showed better than expected results. This important efficacy data has helped us to design a shorter trial requiring fewer patients. Following detailed discussions with the FDA, we may be in a position to successfully complete our clinical development of SNT-MC17/idebenone in Friedreich's Ataxia in the US ahead of our original plans, which is obviously positive news for the FRDA community."

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Note to Editor

For an update on the Company's filing strategy in the EU, please refer to today's news release "Santhera Intends Early Filing in Europe for SNT-MC17/idebenone in Friedreich's Ataxia".

About Santhera

Santhera Pharmaceuticals (SWX:SANN) is a Swiss specialty pharmaceutical company focusing 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 four clinical-stage development programs, three of which are investigating its lead compound, SNT-MC17/idebenone, in the treatment of Friedreich's Ataxia (FRDA), Duchenne Muscular Dystrophy (DMD) and Leber's Hereditary Optic Neuropathy (LHON). The fourth clinical program is investigating JP-1730/fipamezole for the treatment of Dyskinesia in Parkinson's Disease (DPD) in cooperation with Juvantia, the compound's owner. The most advanced program, SNT-MC17/idebenone in FRDA, is in Phase III clinical development while the other clinical programs are in Phase II. For further information, please visit www.santhera.com.

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