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Santhera Intends Early Filing in Europe for SNT-MC17/idebenone in Friedreich's Ataxia

Accelerated Approval Timelines Based on Positive Clinical Data from NIH Collaborative Trial and New EU Guidelines for Small Patient Populations

Liestal, Switzerland, January 31, 2007 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, announces today that it plans to file, ahead of schedule, the Marketing Authorization Approval (MAA) for its lead compound SNT-MC17/idebenone in Friedreich's Ataxia (FRDA) in Europe in summer 2007. This decision follows discussions with representatives from regulatory authorities of several EU Member States, emphasizing the positive data from the Company's collaborative clinical trial with the US National Institutes of Health (NIH). The results of this study showed improvement of neurological parameters and activities of daily living scores in FRDA patients after treatment with intermediate and high doses of SNT-MC17/idebenone for six months. The application for marketing authorization based on these positive data is fully supported by Takeda, Santhera's European marketing partner for SNT-MC17/idebenone for FRDA.

Santhera's early filing strategy takes advantage of new EU regulatory guidelines covering drug development for small patient populations. These guidelines aim to address patient needs by facilitating the approval of product candidates developed to treat diseases affecting only a small number of patients in the EU.

Santhera currently intends to file an MAA for SNT-MC17/idebenone for the treatment of FRDA during summer 2007. The filing, under the new EU regulatory guideline, is based on the positive data obtained in a clinical trial conducted in collaboration with the NIH, the results of which were presented at the 3rd International Friedreich's Ataxia Scientific Conference in Bethesda, Maryland, from November 10 to 12, 2006. Santhera believes that SNT-MC17/idebenone has the potential to be granted European marketing approval for the treatment of FRDA in the second half of 2008, approximately half a year earlier than originally communicated.

Despite the early filing strategy, Santhera will continue its ongoing Phase III clinical trial with SNT-MC17/idebenone in Europe to collect additional safety and efficacy data particularly for the high dose in a wider population of FRDA patients. The Company will amend the study protocol based on the findings of the NIH study and will focus more on evaluating the benefits of SNT-MC17/idebenone on the neurological aspects of FRDA. Consequently, cardiomyopathy will be dropped as

an inclusion criterion for the study. Submission for Ethics approval of the amendments to the protocol is expected shortly.

Klaus Schollmeier, Santhera's CEO, commenting on today's announcement said: "If everything goes according to plan with our revised regulatory strategy, the chances are good that our marketing partner Takeda could launch our first product on the market in Europe in the second half of 2008. This is good news both for Santhera and for FRDA patients who are in great need of the first approved treatment for this devastating disease. I am glad that we have the full support for our accelerated regulatory strategy from Takeda, our European marketing partner for SNT-MC17/idebenone in Friedreich's Ataxia."

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Note to Editor

For more details regarding the EU "Guideline on Clinical Trials in Small Populations", see www.emea.eu.int/pdfs/human/ewp/8356105en.pdf. For an update on the Company's development strategy in the US, please refer to today's news release "Santhera Updates Development Strategy for SNT-MC17/idebenone in Friedreich's Ataxia in the US".

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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