



Swissmedic Accepts Santhera's Filing of SNT-MC17 in Friedreich's Ataxia

Liestal and Lachen, Switzerland, October 4, 2007 – Santhera Pharmaceuticals (SWX:SANN, "Santhera"), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, and Takeda Pharma AG ("Takeda"), jointly announced today that Swissmedic, the Swiss regulatory authority, has accepted the filing of an application for authorization for Santhera's lead compound SNT-MC17 (INN: idebenone, originally developed by Takeda) for the treatment of Friedreich's Ataxia (FRDA). SNT-MC17 has shown clinical efficacy in FRDA patients on neurological and cardiac endpoints in several clinical trials and proved to be well tolerated in all studies so far. Upon approval, the product will be marketed in Switzerland by Santhera's partner Takeda. The acceptance of the marketing authorization application in Switzerland follows shortly after the application for marketing authorization in the EU.

The dossier submitted to Swissmedic includes efficacy data generated in the collaborative study with the US National Institutes of Health (NIH) analyzing a variety of neurological and cardiac outcome measures. The file is supported by data from earlier clinical trials in FRDA conducted by academic institutions that demonstrated efficacy primarily in the treatment of the cardiac symptoms of this devastating disease. The safety package consists of data generated by Santhera with SNT-MC17 and Takeda in its earlier preclinical and clinical development program with idebenone. The Swiss application for authorization recommends a starting dose of 450 mg/day for patients below 45 kg body weight and 900 mg/day for patients of 45 kg or above body weight, with the option for the treating physician to use higher doses if needed. The dosing recommendations as well as the data package of the Swiss filing are equivalent to the EMEA filing.

There is an estimated population of 100 to 200 FRDA patients living in Switzerland. An application for orphan drug status has been filed with Swissmedic but will be reviewed independently. Santhera and Takeda believe that the compound has the potential to be granted marketing approval in Switzerland for the treatment of FRDA in the second half of 2008.

Upon marketing approval, SNT-MC17 will be distributed by Takeda Pharma AG. In Switzerland, Takeda has obtained a temporary authorization in May 2004 for its idebenone, which is fully reimbursed to treat cardiomyopathy in FRDA patients. This temporary status will be revoked once SNT-MC17 is approved and Takeda will subsequently switch to Santhera's product.

Klaus Schollmeier, Santhera's CEO, commented: "We are excited about Swissmedic's acceptance of our marketing authorization application. SNT-MC17 has shown clinically relevant improvements of neurological and cardiac symptoms associated with FRDA. If everything goes according to plan,

we may be able to launch SNT-MC17 in Switzerland still in 2008, thus ensuring a timely transition from the temporary to the full registration”.

Jean-Luc Delay, CEO of Takeda Pharma AG, said: “We have been able to bring notable benefit to Swiss FRDA patients on the basis of idebenone's temporary authorization. Thanks to our joint efforts with Santhera, we now look forward to extend the patient population eligible for this first, fully approved therapeutic therapy. In addition, FRDA patients could benefit from the higher dosing option of SNT-MC17 as supported by clinical evidence.”

About Friedreich's Ataxia (FRDA)

Friedreich's Ataxia (FRDA) is a rare but severe genetic neuromuscular disorder that results in the degeneration of an individual's nerve and muscle tissue. This disorder causes loss of muscle control, uncoordinated movements, muscle wasting and thickening of heart walls which frequently leads to a shortened life span. FRDA affects both Caucasian males and females equally and it is estimated that about 20,000 patients suffer from the disease in both North America and Europe. Average life expectancy for FRDA patients is limited to approximately 35 to 50 years.

The disorder results from a genetic defect in the gene encoding for *frataxin*. Reduced levels of this protein ultimately result in impaired energy production in mitochondria, the cells' energy production centers, and elevated oxidative stress. Tissues that have the highest need for energy, in particular nerve and cardiac tissues, are primarily affected by *frataxin* deficiency resulting in pathological changes in heart muscle anatomy and function and loss of nerve cells. SNT-MC17 is believed to improve the balance and flow of electrons within the mitochondria, therefore increasing the energy production within nerve and muscle cells of FRDA patients, protecting these cells from cell death. A number of clinical trials have provided strong evidence that SNT-MC17 may offer an effective treatment option for FRDA associated heart wall thickening (cardiomyopathy). In addition, data from the collaborative NIH clinical trial suggest positive effects on neurological function.

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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-

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licensed from Novartis. The most advanced program, SNT-MC17 in FRDA, is currently under review for marketing approval in the EU and will be submitted shortly in Canada. The compound is also in Phase III clinical development for FRDA in the US while the while the other clinical programs are in Phase II. For further information, please visit www.santhera.com.

About Takeda Pharma AG

Takeda Pharma AG is one of the top 20 pharmaceutical companies in Switzerland, and one of the fastest growing. It is a subsidiary of Takeda Pharmaceuticals Corporation, Japan (TSE:4502), a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products.

Aiming to become an "R&D-driven world-class pharmaceutical company", Takeda is enhancing its R&D pipeline by concentrating its management resources for that purpose in the following selected core therapeutic areas:

- * cardio-metabolic diseases,
- * oncology and urological diseases
- * central nervous system disorders, bone/joint diseases
- * gastroenterological diseases

Additional information about Takeda Pharma is available through its website, www.takeda.ch.

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