



European EMEA acceptance of Marketing Authorization Application filing for SNT-MC17 in Friedreich's Ataxia by Santhera

Liestal, Switzerland and Osaka, Japan, August 16, 2007 – Santhera Pharmaceuticals (SWX: SANN, "Santhera"), a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, and Takeda Pharmaceutical Company Limited (TSE:4502, "Takeda"), jointly announced today that the European Medicines Agency (EMA) has accepted the filing of the Marketing Authorization Application (MAA) for Santhera's lead compound SNT-MC17 (INN: idebenone, originally developed by Takeda) for the treatment of Friedreich's Ataxia (FRDA). SNT-MC17, which has been granted orphan drug designation in the EU, could become the first approved product for the treatment of FRDA and will be marketed in Europe by Santhera's partner Takeda. SNT-MC17 has shown clinical efficacy in FRDA patients on neurological as well as cardiac endpoints in several clinical studies and proved to be well tolerated in all studies so far.

In a recently completed clinical trial conducted in collaboration with the US National Institutes of Health (NIH), Santhera tested the efficacy of three doses of SNT-MC17 in patients with FRDA. Study results were announced in fall 2006. The MAA file includes data generated in this collaborative study with the NIH analyzing a variety of neurological and cardiac outcome measures, 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 MAA 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 MAA file includes safety data generated by Santhera with SNT-MC17 as well as safety data from Takeda generated in its earlier preclinical and clinical development program with idebenone for the treatment of Alzheimer's disease. Santhera believes that the compound has the potential to be granted European marketing approval for the treatment of FRDA in the second half of 2008.

A milestone payment of EUR 3 million to Santhera from its European marketing partner Takeda is triggered by the EMA's acceptance of the SNT-MC17 MAA filing.

Santhera has decided, despite the MAA filing, to continue its ongoing Phase III clinical trial with SNT-MC17 in Europe to collect additional safety and efficacy data in a wider population of FRDA patients, particularly for doses up to 1350 mg/day and 2250 mg/day in the two body weight groups. Santhera amended the study protocol based on the findings of the NIH study to primarily evaluate the benefits of SNT-MC17 on the neurological aspects of FRDA. Santhera also offers all FRDA

patients that participate and complete the EU Phase III trial the opportunity to enroll in an open label extension study where patients will receive high dose SNT-MC17.

Klaus Schollmeier, Santhera's CEO commenting on today's announcement said: "We are excited about filing the MAA submission for our first product. This was achieved as a combined effort of our specialists and the support we have received from our business partners, in particular from our marketing partner Takeda. Everyone at Santhera is very positive that we may be able to provide Friedreich' Ataxia patients with the first pharmaceutical product that is approved for the treatment of this devastating disease."

Yasuchika Hasegawa, Takeda's President said: "We are pleased with this important progress in development of SNT-MC17 for FRDA by Santhera, while there is currently no effective pharmacological treatment for this disease. We expect that our joint efforts with Santhera bring notable benefit to the patients with FRDA."

In August 2005, Santhera and Takeda signed an agreement under which Santhera granted exclusive marketing rights for SNT-MC17 in FRDA in the EU and in Switzerland to Takeda. Earlier this month, the two companies have announced the extension of this marketing partnership in Europe to cover also SNT-MC17's second potential indication, Duchenne Muscular Dystrophy (DMD).

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 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 five clinical-stage development programs, three of which are investigating its lead compound, SNT-MC17 (INN: idebenone), in 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. The most advanced program, SNT-MC17 in FRDA, is currently in Marketing Authorization Application process in Europe and in Phase III clinical development in the US while the other clinical programs are in Phase II. For further information, please visit www.santhera.com.

About Takeda

Located in Osaka, Japan, Takeda (TSE:4502) is 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:

- * lifestyle-related diseases,
- * oncology and urological diseases
- * central nervous system disorders, bone/joint diseases
- * gastroenterological diseases

Additional information about Takeda is available through its corporate website, www.takeda.com.

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