Initiation of Pivotal Phase III Study with Catena®/Sovrima® (Idebenone) in Duchenne Muscular Dystrophy

Liestal, Switzerland and Osaka, Japan, September 2, 2009 – Santhera Pharmaceuticals (SIX: SANN, "Santhera"), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, and Takeda Pharmaceutical Company Limited (TSE: 4502, "Takeda") announced today that Santhera has initiated the pivotal Phase III study with Catena®/Sovrima® (INN: idebenone) for the treatment of Duchenne Muscular Dystrophy, one of the most common and devastating types of muscle degeneration. The 12-month DELOS study will enroll up to 240 patients in 25 centers in Europe and North America. The start of patient enrollment into this Phase III study has triggered a milestone payment of EUR 5 million from Takeda, marketing partner in the European Union and Switzerland, already received by Santhera.

The Phase III study named DELOS (DuchEnne Muscular Dystrophy Long-term IdebenOne Study) is a double-blind, randomized, placebo-controlled clinical trial evaluating Catena®/Sovrima® in up to 240 ambulatory and non-ambulatory patients aged 10 to 18 years. The safety, tolerability and efficacy of one dose of Catena®/Sovrima® (900 mg/day) will be compared to placebo over a treatment period of 12 months. The primary endpoint of the DELOS study is the change from baseline to week 52 in respiratory function measured by peak expiratory flow. Secondary endpoints include other respiratory parameters, muscle strength and motor function over the treatment period and improvement in quality of life amongst others. The study is expected to involve up to 25 study centers in Europe, the United States and Canada.

The principal investigator of the DELOS study is Professor Gunnar Buyse, Professor of Pediatrics & Child Neurology at the University Hospitals Leuven, Belgium. Dr Richard Finkel, MD, Director of Neuromuscular Programs at the Children's Hospital of Philadelphia (PA) will act as Lead Investigator in the United States and Canada. The study design, dose selection and duration of the treatment period of the DELOS study are based on the positive results Santhera obtained in a Phase II study and were pre-discussed with the US Food and Drug Administration as well as with the European Medicines Agency. Furthermore, both agencies agreed that, subject to positive outcome, a single pivotal study could suffice for approval.

Professor Gunnar Buyse said: "Duchenne Muscular Dystrophy is a devastating neuromuscular disease which affects the skeletal muscles, including the respiratory muscles as well as the heart. Following encouraging preclinical findings in a placebo-controlled, long-term trial in a disease-relevant model, a Phase II clinical trial demonstrated efficacy of this drug on early respiratory and

cardiac parameters, in which a decline represents life-threatening complications of the disease. We hope to confirm these observations in the DELOS Phase III study and, as a result, develop Catena®/Sovrima® as the first drug approved to treat Duchenne Muscular Dystrophy."

Klaus Schollmeier, Chief Executive Officer of Santhera commented: "The start of the DELOS study is another significant landmark in the development of Catena®/Sovrima® as potential first therapies for rare neuromuscular diseases. Currently, sufferers and physicians have no treatment options for such devastating diseases. The high unmet medical need is reinforced in the frequent, positive feedback we continue to receive from Canada, where Catena® is already available to treat Friedreich's Ataxia."

"The partnership with Santhera is a good example of our commitment to bring superior pharmaceutical products to those who need them," commented Erich Brunn, CEO of Takeda Pharmaceuticals Europe Limited, Takeda's wholly-owned UK-based subsidiary for overseeing pan-European sales and marketing. "Through close cooperation with Santhera, we will continue our efforts to bring this new treatment option to patients with Duchenne Muscular Dystrophy and healthcare providers as early as possible."

In August 2007, Santhera and Takeda entered into an agreement to extend their existing collaboration for Friedreich's Ataxia to include Duchenne Muscular Dystrophy. Under this second agreement, Takeda granted Santhera a certain right to access and use Takeda's data on idebenone, and Santhera granted Takeda an exclusive right to commercialize the product in the European Union and Switzerland under the brand name Sovrima®. The deal terms included an upfront payment from Takeda and entitle Santhera to development milestones of up to EUR 18 million in total, whereof EUR 5 million became payable upon dosing into this pivotal study.

About Duchenne Muscular Dystrophy

Duchenne Muscular Dystrophy is one of the most common and devastating types of muscular degeneration. The disease affects boys of all ethnicities with an onset of symptoms as early as three to five years of age. Males affected by Duchenne Muscular Dystrophy suffer from an X-linked recessive inherited disease, caused by mutations in the gene that encodes dystrophin. In healthy individuals, this protein stabilizes the muscle cells during cycles of contraction and relaxation. Dystrophin acts as a mechanical linker between the contracting elements and cell surface proteins in each muscle cell. Loss of this protein results in a characteristic form of progressive muscle weakness and wasting throughout the body. Disease symptoms initially start in the legs and pelvis and spread to shoulders, neck and arm muscles. Other complications include skeletal deformation, respiratory distress and cardiac failure. As the disease progresses, sufferers become confined to a wheelchair during their teenage years. The average life expectancy for Duchenne Muscular Dystrophy patients is 30 to 35 years. An estimated 30,000 males in Europe and North America suffer from Duchenne Muscular Dystrophy. With no effective medication available for chronic use, treatment focuses on supportive aids aimed at delaying or alleviating the symptoms.

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of small-molecule pharmaceutical products for the treatment of severe neuromuscular diseases, an area of high unmet medical need which includes many orphan indications with no current therapy. Santhera's first product, Catena® to treat Friedreich's Ataxia, is marketed in Canada and in a well-advanced Phase III development program. Recently published study results show that the Company's second compound JP-1730/ fipamezole is efficacious in reducing levodopa-induced Dyskinesia in Parkinson's Disease. For further information, please visit the Company's web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals.

About Takeda

Located in Osaka, Japan, Takeda 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. Additional information about Takeda is available through its corporate website, www.takeda.com.

Sovrima® is a trademark of Takeda Pharmaceutical Company Limited.

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