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Santhera Enrolls Last Patient in RHODOS Study Evaluating Catena® in Leber's Hereditary Optic Neuropathy

Liestal, Switzerland, August 3, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today that recruitment has been completed for its six-month RHODOS study evaluating Catena® in Leber's Hereditary Optic Neuropathy (LHON). LHON is a rare genetic eye disease that leads to a rapid loss of central vision and ultimately to blindness as a result of degenerated nerve cells in the retina and optic nerve. Worldwide, an estimated 35,000 predominantly male patients suffer from this mitochondrial disorder.

The clinical study named RHODOS (Rescue Of Hereditary Optic Disease Outpatient Study) is a double-blind, randomized, placebo-controlled study of six months treatment duration investigating the efficacy of one dose of Catena® (INN: idebenone, 900 mg/day) in the treatment and prevention of LHON compared to placebo. The three study centers in Munich (Germany), Newcastle (United Kingdom) and Montréal (Canada) have enrolled a total of 85 acute patients as well as patients experiencing vision loss for up to five years. Study participants have been randomized with a ratio of 2:1 to the active dose and placebo, respectively. The primary endpoint is the improvement of visual function as assessed by visual acuity (logMAR). The RHODOS study also evaluates the mitigation of further visual loss as assessed by logMAR and the proportion of patients in which vision has improved in at least one eye. As of today, 47 patients have already completed the study.

"Catena® is the first drug that has ever been clinically investigated in a randomized, placebo controlled study in LHON. By completing enrollment of the RHODOS study, we have achieved an important milestone in the development of a first potential therapy," said Klaus Schollmeier, Chief Executive Officer of Santhera. "The extra efforts of our clinical investigators for the recruitment of this study reflect the significant unmet medical need in this rare disease. We believe that Catena® has the potential to be the first approved medicine in the treatment of LHON."

Santhera's clinical development program is based on a compelling scientific rationale suggesting that Catena® may delay, lessen or protect from vision loss in LHON. This is based on the drug's principal mode of action as an enhancer of mitochondrial electron flux and energy production as well as its antioxidant properties which may protect the retinal and optic nerve cells in LHON patients. The Company's development program has been granted orphan drug status by both the US Food and Drug Agency and the European Medicines Agency.

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About Leber's Hereditary Optic Neuropathy (LHON)

Patients suffering from LHON typically have one of three different point mutations of the genetic code within the mitochondria, the energy-producing centers in each cell. These mutations lead to the reduction of cellular energy production which results in cell damage and death of optic nerve cells. The factor determining why only optic nerve cells become affected is unclear. Blurring of central vision and color desaturation usually mark the beginning of the symptomatic phase of LHON. The effects of the disease are rapid and severe, with damage to certain nerve cells in the retina leading to blindness within a few months after the onset of first symptoms. Within approximately twelve months of visual loss in one eye, over 97% of patients experience vision loss in the second eye, subsequently resulting in legal blindness. Worldwide an estimated 35,000 patients, predominantly otherwise healthy adult males, suffer from LHON. Currently, there is no effective treatment available to prevent the rapid loss of vision, representing a high unmet medical need.

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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. Data of a second pivotal Phase III study are expected for the first half of 2010. The drug has also shown efficacy in a clinical trial as a potential treatment for Duchenne Muscular Dystrophy. Recently reported results from a clinical trial demonstrate efficacy of JP-1730/fipamezole in reducing levodopa-induced Dyskinesia in Parkinson's Disease. The development portfolio consists of additional clinical programs, and will be grown further through in-licensing and reprofiling of existing compounds, driven by Santhera's in-house expertise in pharmacology. For further information, please visit the Company's web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals.

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