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Santhera Enters Agreement with Columbia University to Investigate Additional Potential of Catena® in MELAS

Liestal, Switzerland, June 26, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today a collaboration with Columbia University in New York to investigate Catena® in a Phase II study as treatment of MELAS (Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like episodes). The MELAS syndrome is a rare but devastating multisystem disorder that affects the brain, nervous system, muscles and cognitive abilities. Currently, there are no approved therapies available or in development to help people with MELAS. Today’s announcement follows shortly after a similar collaboration between Santhera and the US National Institutes of Health to investigate Catena® in Primary Progressive Multiple Sclerosis.

The MELTIMI (MELAS Trial of Idebenone using MRS) trial is a Phase II double-blind, placebo-controlled study investigating the safety and efficacy of two doses of Catena® (INN: idebenone) versus placebo. The primary endpoint of the proof-of-concept study is the change in cerebral lactate concentration from baseline to week four as assessed by Magnetic Resonance Spectroscopy (MRS). The MELTIMI study will also investigate additional endpoints such as venous lactate levels, fatigue and quality of life. The lactate level is considered a viable biomarker associated with the neurological impairment in MELAS. Overall, the MELTIMI study will enroll 21 patients aged between 8 and 65 years. Further details of the study protocol including contact details of the study center are registered under www.clinicaltrials.gov (identifier: NCT00887562).

The MELTIMI study is being performed at Columbia University. Under the agreement, the Neurological Institute of Columbia University is conducting the clinical trial while Santhera is supplying the study medication and contributes data management and other support. The Company has exclusive rights to the data for regulatory purposes.

Thomas Meier, Chief Scientific Officer of Santhera, commented: “MELAS is a devastating multi-system syndrome for which no effective treatment is available or in clinical development. There is a strong scientific rationale that suggests that Catena® may protect patients with MELAS from neuronal damage, based on the drug’s ability to enhance mitochondrial function. We are very pleased to announce this collaboration with Columbia University, a leading academic research university. Our goal is to validate cerebral lactate level as biomarker and to conduct a proof of concept study of Catena® in MELAS.”

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About the Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like Episodes

The Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like Episodes (MELAS) syndrome is a progressive and devastating condition that affects many of the body's systems, particularly the brain and nervous system (*encephalo-*) and muscles (*myopathy*). The most characteristic symptoms of MELAS are recurring, stroke-like episodes in which severe, migraine-like headaches are followed by vomiting and seizures. Repeated stroke-like episodes can progressively damage the brain, leading to vision loss, problems with movement, and dementia. Other symptoms include short stature, diabetes, exercise intolerance and hearing loss. Most people suffering from MELAS have an accumulation of lactic acid (*lactic acidosis*) in the blood which can lead to vomiting, abdominal pain, extreme tiredness, muscle weakness, and difficulty breathing. Elevated levels of lactic acid in the brain are considered to be part of the underlying causes that lead to stroke-like episodes and brain tissue damage. The maternally inherited multisystem disorder runs in families and manifests in both sexes. First signs and symptoms usually appear already in childhood. MELAS is associated with a shortened life-expectancy.

The MELAS syndrome is caused by a mutation in the mitochondrial genome leading to impaired function of the mitochondrial respiratory chain. Catena® has been shown to enhance the electron flow in the electron transport chain and increase cellular energy production. The drug is also active in scavenging reactive oxygen species thereby protecting the cell from oxidative stress. Catena® is crossing the brain-blood barrier and is readily taken up by cells.

Current treatment options are limited to symptomatic management of seizures, diabetes and other medical complications. There are no approved therapies available or in clinical development to help people with MELAS. In the absence of reliable epidemiological studies, the prevalence is assumed to be several thousands patients each in Europe and in the United States. Existing prevalence numbers indicate regional hot spots and a high degree of under-diagnosis. Given the orphan nature of the disease and the associated high unmet medical needs, the program with Catena® qualifies for application of orphan drug designations.

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the discovery, 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 the second pivotal Phase III trial in Europe 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. For further information, please visit the Company's Web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals.

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