



Santhera Starts Phase IIb Clinical Trial with JP-1730 in Dyskinesia in Parkinson's Disease

Liestal, Switzerland and Turku, Finland, November 9, 2007 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, and Juvantia Pharma Ltd, a Finnish biotechnology company, announced today that the first patient has been enrolled into a Phase IIb clinical trial to evaluate JP-1730 (INN: fipamezole) for the treatment of Dyskinesia in Parkinson's Disease (DPD). The study is designed to confirm the dual efficacy of the compound observed previously in a successful proof-of-concept trial. The Phase IIb trial, named FJORD, specifically investigates JP-1730's capacity to reduce dyskinetic movements and to extend the anti-parkinsonian action of levodopa. Results are expected in the second half of 2008.

The Phase IIb trial named FJORD (Eipamezole from Juvantia fOR treatment of Dyskinesia) evaluates JP-1730 in DPD, using a double-blind, randomized, placebo-controlled dose response design involving 152 patients. The safety and efficacy of three escalating doses of JP-1730 (30, 60 and 90 mg tid using a newly developed fast dissolving tablet) will be compared to placebo over a treatment period of 28 days. The primary endpoint is the reduction of dyskinetic movements in PD patients as assessed by the newly developed "levodopa-induced dyskinesia scale" (LIDS) for rating DPD. Secondary endpoint is the efficacy of the three doses in extending levodopa anti-parkinsonian action, being assessed using an electronic patient diary. The clinical trial will evaluate additional benefits of JP-1730, such as the impact on cognitive functions measured by a neuropsychological testing battery.

The FJORD study will enroll patients with advanced PD and will be conducted at 30 sites in the US and India. Results of the trial are expected in the second half of 2008. The study design, dose selection and duration of the treatment period have been based on the positive results obtained in an earlier Phase IIa proof-of-concept trial in collaboration between Juvantia and the US National Institutes of Health in a smaller patient population. The goal of the FJORD study is to provide data on efficacy and safety of JP-1730 as well as information on feasible endpoints for the planning and execution of a subsequent Phase III development of the compound in DPD in the US and EU.

Klaus Schollmeier, Santhera's CEO commenting on today's announcement said: "This DPD trial is our largest study to-date. Importantly, DPD is also the largest indication that Santhera is currently working on in the clinic. Based on the encouraging proof of concept data from Juvantia, we have now designed this trial to confirm the compound's potential dual efficacy profile in a larger patient cohort. The data obtained should provide final insight to complete the development of this drug candidate in order to bring this important new product to patients."

Santhera Starts Phase IIb Clinical Trial with JP-1730 in DPD

November 9, 2007 / Page 2 of 4

Keijo Väkiparta, Chairman of Juvantia, said: "Together, Santhera and Juvantia have moved efficiently to initiate the Phase IIb trial with JP-1730 in DPD as planned. The current clinical program in DPD represents an excellent opportunity for Juvantia to drive the further development of this important product."

In July 2006, Santhera and Juvantia signed a collaboration agreement to advance the development of Juvantia's compound JP-1730 for the treatment of patients suffering from DPD. Under the agreement, Santhera is responsible for conducting and funding further development work to generate data required for commencement of Phase III trials. Santhera has a call option to secure all rights to the product candidate via the acquisition of Juvantia at any time before December 31, 2008 with a possible extension to June 30, 2009.

The US Food and Drug Administration (FDA) has granted Juvantia a fast track designation for the compound for the treatment of dyskinesia in advanced PD. In the EU, patent protection was recently granted for the novel formulation of JP-1730 until 2023.

About Dyskinesia in Parkinson's Disease

Parkinson's disease (PD) is the second most common neurodegenerative disease. Its symptoms include uncontrollable tremor of the extremities, rigidity of muscles and jerky movements, stooped posture, expressionless face and difficulty in any function requiring a high degree of motor coordination, such as walking, writing, and talking. Current standard medical treatment for PD is based on levodopa. Over time, as the disease progresses, the beneficial effects of this therapy diminish and, for example, additional movement disorders appear and become gradually very severe. As a result, patients often require extended periods of hospitalization or placement in a full-time nursing environment. In advanced disease stages, movement disorders include dyskinesias (DPD) which can be described as chaotic movements of limbs, face, tongue and the body, typically during the peak on-time of the levodopa effect. These complications derive principally from long-term levodopa use, but there is no long-term solution to avoid using levodopa. It is estimated that within 5 years of initiating levodopa treatment approximately 20% of all PD patients develop troublesome dyskinesia affecting their daily living.

About Fipamezole

Fipamezole is an antagonist of the adrenergic alpha-2 receptor and offers a novel and unique mode of action to treat motor dysfunctions in PD, such as dyskinesia (DPD). The rationale behind the development of fipamezole is to increase noradrenergic release in certain areas of the brain, resulting in a rebalancing of the distorted brain network and alleviating symptoms of advanced PD such as dyskinesias, motor fluctuations, orthostatic hypotension and cognitive impairment. In addition, fipamezole is believed to extend the beneficial effects of commonly used levodopa (prolonged on-time) and other dopamine agonists without the negative side effects associated with these treatments. Such therapy is expected to improve the quality of life of Parkinson's patients.

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Santhera Starts Phase IIb Clinical Trial with JP-1730 in DPD

November 9, 2007 / Page 3 of 4

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

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Santhera Starts Phase IIb Clinical Trial with JP-1730 in DPD

November 9, 2007 / Page 4 of 4

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