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Santhera's FJORD Phase IIb Study Demonstrates Efficacy of JP-1730/Fipamezole for the Treatment of Dyskinesia in Parkinson's Disease

Liestal, Switzerland, June 30, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announced today positive data from its Phase IIb study (FJORD). The key finding of the trial is that JP-1730/fipamezole reduces levodopa-induced dyskinesia in Parkinson's patients. This beneficial effect was not associated with a worsening of Parkinsonian features of the disease. The data additionally suggest that JP-1730/fipamezole reduces "off time" and improves cognitive function as well as clinical global impression in dyskinesia. The compound was found to be safe and well tolerated.

The FJORD study was a double-blind, randomized, placebo-controlled, multiple dose-escalating study of the safety, tolerability and efficacy of JP-1730/fipamezole in the treatment of levodopa-induced dyskinesia in Parkinson's Disease patients. The study investigated the efficacy of three doses (30, 60 and 90 mg) compared to placebo over a treatment period of 28 days in 179 patients enrolled at a total of 33 sites in the US (26) and India (7). The primary study endpoint was the suppression of levodopa-induced dyskinesia as measured by the Levodopa Induced Dyskinesia Scale (LIDS) [1]. The LIDS is a modified version of the Abnormal Involuntary Movement Scale, an evaluation tool widely used in clinical research.

Webcast / Teleconference

At **15.00 CET / 14.00 UKT / 09.00 EST** on **June 30, 2009**, Santhera's management will discuss the results of the FJORD study. Anyone interested in participating may join either the **webcast on www.santhera.com/webcast** or the **teleconference (ID: 17327356)** using one of the following dial-ins

Germany	0800 101 4960
Switzerland	056 580 00 07 (local call)
United Kingdom / International	+44 (0) 1452 555 566
United States	1 866 966 9439

The webcast will be available for playback one hour after the presentation ends.

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Ongoing medical and scientific oversight of the FJORD study was provided by a Scientific Committee comprising a subgroup of the participating US Parkinson's specialists and chaired by Professor Peter LeWitt, MD, Departments of Neurology, Henry Ford Hospital & Wayne State University School of Medicine, Detroit, Michigan (USA), and Principal Investigator of the FJORD study.

A pre-specified secondary analysis of 116 patients enrolled at the 26 participating US centers showed that at the highest dose of JP-1730/fipamezole tested (90mg), patients experienced a significant reduction in levodopa-induced dyskinesia as compared to placebo ($p=0.047$, $n=29$), assessed by the LIDS. In addition, a highly significant dose dependency ($p=0.0066$) was demonstrated. This beneficial effect was not associated with a clinically relevant worsening of Parkinsonian features of the disease (a secondary endpoint assessed with a standard rating instrument, the Unified Parkinson's Disease Rating Scale, UPDRS III). A responder analysis, which focused on those patients experiencing (i) a reduction in dyskinesia and (ii) no worsening of Parkinsonism in the investigator's clinical global impression, showed a higher proportion of responders in the 90mg group as compared to placebo. Another positive outcome of the US subgroup analysis was a significant treatment-dose effect in the reduction of hours spent with diminished mobility ("off time"), as measured by patients using all-day self-assessment ratings.

The Committee carried out the US subgroup analysis due to strong evidence of inhomogeneity between the US and Indian study populations with respect to several baseline clinical characteristics differentiating the two patient populations. Of particular concern were the usage patterns and doses of levodopa and additional clinical features that raised doubts about the rationale for merging study data.

The original primary outcome, based on a change in the LIDS rating in the combined US and Indian study population ($n=179$), showed a positive trend for benefit but did not reach significance. However, the strong evidence of efficacy in the US subgroup, which comprised 65% of the study population, led to the Committee's endorsement for further development of JP-1730/fipamezole in this indication.

Professor Peter LeWitt commented: "Levodopa-induced dyskinesia are a common and frequently disabling problem of advanced Parkinson's Disease for which treatment options are limited. The FJORD Scientific Committee is encouraged by the US study site findings. Given these results and the good safety and tolerability observed, the Committee recommends proceeding with the development of the drug, possibly including higher doses than those previously tested."

Klaus Schollmeier, Chief Executive Officer of Santhera, commented: "I am pleased about the outcome of our FJORD study. We fully share the Committee's view that the FJORD study data provide a clear path forward for the further development of JP-1730/fipamezole in the treatment of dyskinesia. We now expect to partner this program to bring this important compound to the market as expeditiously as possible."

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Further detailed analysis of the data from the FJORD Phase IIb study will be presented at upcoming medical meetings and in peer-reviewed publications.

About Dyskinesia in Parkinson's Disease

Parkinson's Disease is the second most common neurodegenerative disease. Doctors prescribe levodopa and other dopaminergic compounds as standard therapy. Over time, as the disease progresses, the beneficial effects of this medication often diminish and additional movement disorders can appear (sometimes quite severe). These movement disorders include dyskinesia which can be described as sudden uncontrollable, often chaotic movements of limbs, face, tongue and body. These complications derive principally from long-term levodopa use, but there is currently no alternative to using levodopa or dopamine agonists. It is estimated that approximately 400,000 patients in Europe and North America are affected by troublesome dyskinesia associated with their levodopa therapy.

About Fipamezole

Fipamezole is an antagonist of the adrenergic alpha-2 receptor and offers a novel and unique mode of action to treat Dyskinesia in Parkinson's Disease. The rationale behind the development of fipamezole is to increase noradrenergic release in certain areas of the brain, resulting in rebalancing of the distorted brain network and alleviating symptoms of advanced Parkinson's Disease such as dyskinesia, motor fluctuations, orthostatic hypotension and cognitive impairment. In addition, fipamezole is believed to extend the beneficial effects of commonly used levodopa (prolongs "on-time") and other dopamine agonists without the negative side effects associated with these treatments. JP-1730/fipamezole has been tested previously in a study conducted at the US National Institutes of Health in Bethesda, Maryland, in which patients with advanced Parkinson's disease achieved a reduction in dyskinesia and fluctuations in mobility [2]. Such therapy is expected to improve the quality of life of Parkinson's patients.

References

[1] Peter A. LeWitt ea: Validating Rating Performance of a New Rating Scale for Levodopa-Induced Dyskinesia (LIDS). Poster presented at MDS 13th International Congress of Parkinson's Disease and Movement Disorders, June 2009.

[2] Tzvetelina Dimitrova ea: Alpha-2 Adrenergic Antagonist Effects in Parkinson's Disease. Poster presented at MDS 13th International Congress of Parkinson's Disease and Movement Disorders, June 2009.

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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 a second pivotal Phase III trial 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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