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Santhera Presents Efficacy Data of SNT-317 in Congenital Muscular Dystrophy at International Congress of Myology

Liestal, Switzerland, May 28, 2008 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announces today that positive preclinical data with SNT-317 (INN: omigapil) in Congenital Muscular Dystrophy (CMD) are being presented at the 3rd International Congress of Myology [1] in Marseille, France. Tests in disease-relevant models have shown that SNT-317 prevents apoptosis and ameliorates the pathology of laminin-alpha2 deficient muscular dystrophy. Recently, omigapil was granted orphan drug designation in the European Union for the two most common sub-types of Congenital Muscular Dystrophy.

Omigapil is an anti-apoptotic compound structurally derived from R(-)-deprenyl (selegiline) but unlike selegiline exhibits virtually no monoamine oxidase Type B inhibiting activity and is not metabolized to amphetamines. The efficacy of the compound was tested in dy^W/dy^W mice, a well established animal model for laminin alpha2-deficient muscular dystrophy. SNT-317 was applied orally at a daily dose of 0.1 or 1 mg/kg starting at 3-weeks of age, while control animals were treated with vehicle. The results show that SNT-317 ameliorated key pathology hallmarks of the dy^W/dy^W mouse. Specifically, oral administration of the compound reduced apoptosis in muscle and preserved muscle histology, reduced body weight loss, mitigated skeletal deformation and improved locomotion. Moreover, SNT-317 increased the 50% survival time from ~35 days in vehicle treated dy^W/dy^W mice to ~85 days and ~105 days in dy^W/dy^W mice treated with 0.1 mg/kg and 1 mg/kg, respectively. In addition, it was shown that co-administration of mini-agrin had additive beneficial effects.

Thomas Meier, Chief Scientific Officer of Santhera, commented: "Our preclinical research has shown that SNT-317 reduces apoptosis and preserves muscle histology resulting in increased body weight, mitigated skeletal deformation, improved locomotion and increased life span. Based on these data, we believe omigapil is a potential therapeutic option for certain forms of CMD. At present there are no drugs approved or in advanced clinical development for the treatment of this very devastating disease."

In June 2007, Santhera in-licensed omigapil from Novartis for development in CMD and other neuromuscular diseases. Recently, the European Medicines Agency (EMA) granted orphan drug designation for the compound in CMD with merosin (laminin-alpha2) deficiency (MDC1A) and with collagen VI deficiency (Ullrich Congenital Muscular Dystrophy and Bethlem Myopathy), the two most common subtypes of CMD.

About Congenital Muscular Dystrophy

Congenital Muscular Dystrophy (CMD) refers to a group of inherited neuromuscular disorders which frequently affects infants or young children with life-threatening progressive muscle weakness. The best epidemiological estimate for CMD approximates one patient in every 20,000 to 50,000 newborn children. CMD is characterized by progressive loss of muscle tissue or hypotonia which in severe forms can already affect newborns ("floppy infant syndrome"). Other symptoms include loss of body weight, skeletal deformations and respiratory distress. Complications associated with CMD cause immobility at young age and early mortality. The most common subtypes are Ullrich Congenital Muscular Dystrophy (UCMD) and Bethlem Myopathy (BM), caused by mutations in one of the three collagen VI genes, and MDC1A which is caused by mutations in the gene encoding laminin alpha-2, a protein in the extracellular matrix of muscle cells. No pharmacological therapy is currently available or in advanced clinical development for CMD. Important aspects of disease management include orthopedic surgery of scoliosis, supplementary nutrition to avoid malnutrition and ventilatory support.

[1] Thomas Meier, Michael Erb, Sarina Meinen, Patrizia Barzaghi, and Markus A. Ruegg: Omigapil/SNT-317 prevents apoptosis and ameliorates the pathology of laminin-alpha2 deficient muscle dystrophy, poster PW17-212 presented at the 3rd International Congress of Myology (MYOLOGY 2008) in Marseille, France, organized by the Association Française contre les Myopathies.

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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 Company's most advanced program, SNT-MC17 in FRDA, is under review for marketing authorization in the EU, Switzerland and Canada, and currently in an on-going Phase III clinical trial in the US. The compound has also shown efficacy as a potential treatment in DMD, its second indication. For further information, please visit www.santhera.com.

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