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Santhera's Omigapil Receives Orphan Drug Designation from FDA and EMEA

Liestal, Switzerland, August 15, 2008 – Santhera Pharmaceuticals (SWX:SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announces today that the US Food and Drug Administration (FDA) has granted orphan drug designation to SNT-317/omigapil for treatment of Congenital Muscular Dystrophy. This severe, genetically determined neuromuscular condition frequently affects infants or young children with life-threatening progressive muscle weakness. The decision from the FDA follows shortly after the European Medicines Agency (EMA) granted orphan drug designation for the two most common subtypes of the disease.

Orphan drug legislation in the United States and the European Union are designed to encourage pharmaceutical companies to develop treatments for rare conditions. The FDA and the EMA define orphan diseases as affecting fewer than 200,000 individuals (US) or no more than 5 in 10,000 (EU). Products eligible for orphan drug status enjoy market exclusivity of up to seven (US) and ten (EU) years following the date of marketing approval. Additional incentives include tax credits, fee waivers for regulatory submissions and others.

In 2007, Santhera licensed omigapil from Novartis for development in Congenital Muscular Dystrophy and other neuromuscular diseases. Tests in a disease-relevant model have shown that SNT-317/omigapil prevents apoptosis and ameliorates the pathology of laminin-alpha 2 deficient muscular dystrophy. Preclinical data will be presented at the upcoming 13th International World Muscle Society Congress in Newcastle, United Kingdom, from September 29 to October 2, 2008.

About Congenital Muscular Dystrophy

Congenital Muscular Dystrophy 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 approximates one patient in every 20,000 to 50,000 newborn children. Congenital Muscular Dystrophy 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 the disorder 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 Congenital Muscular Dystrophy.

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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, an area of high unmet medical need which includes many orphan indications with no current therapy. Santhera currently investigates three compounds in five clinical-stage development programs. The Company's first product, SNT-MC17/idebenone, has received a marketing approval with conditions from Health Canada to treat Friedreich's Ataxia and will be marketed under its brand name Catena®. The product is also under review by health authorities in the EU and in Switzerland, while in the United States, a pivotal Phase III trial is recruiting patients. The compound has also shown efficacy in a Phase II clinical trial as a potential treatment for Duchenne Muscular Dystrophy. For further information, please visit the Company's website www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals, registered in Canada and the United States.

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