



Santhera Pharmaceuticals Holding AG
Hammerstrasse 49
CH-4410 Liestal / Switzerland
Phone +41 (0)61 906 89 50
Fax +41 (0)61 906 89 51
www.santhera.com

Santhera Receives Grant from Association Française contre les Myopathies for its Omigapil Program in Congenital Muscular Dystrophy

Liestal, Switzerland, November 3, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today that the French patient advocacy organization Association Française contre les Myopathies (AFM) awarded a grant of CHF 1 million for the development of Santhera's SNT-317 (INN: omigapil) in Congenital Muscular Dystrophy (CMD). This severe, genetically determined neuromuscular condition frequently affects infants or young children with life-threatening progressive muscle weakness. AFM's grant will finance the remaining non-clinical studies needed before the compound can enter clinical development in pediatric patients. A recent publication in *Journal of Pharmacology and Experimental Therapeutics* highlights the beneficial effect of SNT-317/omigapil in a disease-relevant model [1].

Originally developed by Novartis, SNT-317/omigapil was licensed by Santhera in 2007 for development in CMD. In preclinical studies, the compound inhibited GAPDH-Siah1 mediated apoptosis in muscle tissue and reduced body weight loss and skeletal deformation while increasing locomotive activity and protecting from early mortality. Santhera has been granted orphan drug designations by the US Food and Drug Administration and European Medicines Agency for CMD subtypes caused by collagen-VI and laminin-alpha-2 deficiency.

The funding of two non-clinical studies by AFM will enable the clinical development of SNT-317/omigapil in pediatric CMD patients. AFM will be eligible to a success-based repayment of the grant after product launch.

"Receiving this financial support from AFM reinforces our commitment to develop SNT-317/omigapil for CMD. Professional patient advocacy organization such as AFM are tremendously important in advancing translational research into the clinic, particularly for diseases such as CMD for which there is no pharmacological therapy available or in advanced clinical development", said Thomas Meier, Chief Scientific Officer of Santhera.

"AFM's main objective is to pave the way for new treatments that ultimately bring help and hope for patients suffering from rare neuromuscular diseases. SNT-317/omigapil is a promising first therapy for Congenital Muscular Dystrophy. Through this grant, we support Santhera in driving the development of this important compound", says Serge Braun, scientific director of AFM.

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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. A recent epidemiological estimate for Congenital Muscular Dystrophy approximates a prevalence of 0.89 per 100,000. The genetically determined disease 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 Congenital Muscular Dystrophy 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.

Neuromuscular diseases resulting from collagen-VI and laminin-alpha-2 deficiency such as the UCMD, BM and MDC1A subtypes of Congenital Muscular Dystrophy show severe muscle pathology associated with mitochondrial dysfunction and muscle cell apoptosis. Preclinical studies have shown that SNT-317/omigapil reduces apoptosis and preserve muscle histology resulting in increased body weight, mitigated skeletal deformation, improved locomotion and increased life span.

Reference

[1] Michael Erb, Sarina Meinen, Patrizia Barzaghi, Lazar T. Sumanovski, Isabelle Courdier-Fruh, Markus A. Ruegg, and Thomas Meier: **Omigapil ameliorates the pathology of muscle dystrophy caused by laminin-alpha 2 deficiency**. Journal of Pharmacology and Experimental Therapeutics, doi:10.1124/jpet.109.160754

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About AFM

Created in 1958 by a group of patients and their families and recognized as being of public utility in 1976, AFM (French Muscular Dystrophy Association) has a single objective: to defeat neuromuscular diseases. Thanks to French Telethon donations (EUR 104 millions in 2008); the AFM is a major actor of biomedical research for rare diseases in the world. Over the last few years, therapeutic strategies (gene or cell or pharmacological therapies) have demonstrated their effectiveness in animals affected with rare diseases and – for the first selected diseases– in humans. 34 clinical trials are under way or in preparation for 30 different diseases thanks to the AFM support. Beyond rare diseases, the results obtained will also benefit a larger number of people affected with more frequent diseases. For further information, please visit the web site www.afm-telethon.fr.

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the 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 and in a well-advanced Phase III development program. The drug is also investigated in a Phase III study in Duchenne Muscular Dystrophy. Santhera's pipeline consists of three compounds in seven indications including SNT-317/omigapil in Congenital Muscular Dystrophy. For further information, please visit the Company's Web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals.

For further information, contact

Santhera Pharmaceuticals

Thomas Meier, Chief Scientific Officer

Phone: +41 (0)61 906 89 87

thomas.meier@santhera.com

Thomas Staffelbach, Head Public & Investor Relations

Phone: +41 (0)61 906 89 47

thomas.staffelbach@santhera.com

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