



Santhera Pharmaceuticals Holding AG
Hammerstrasse 47
CH-4410 Liestal / Switzerland
Phone +41 (0)61 906 89 50
Fax +41 (0)61 906 89 51
www.santhera.com

Publication Highlights Potential of Santhera's Oral MC4-Receptor Antagonist Program for Treatment of Cancer Cachexia

Liestal, Switzerland, March 20, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today the peer-reviewed publication of preclinical data on melanocortin 4 (MC4)-receptor antagonists for potential treatment of Cancer Cachexia (severe muscle wasting) in PLoS ONE (Publication Library of Sciences ONE [1]). The Company's new orally active compounds significantly increase food intake in healthy animals and prevent cancer-induced body weight loss in disease-relevant models. In vivo data of Santhera's MC4-receptor antagonist program will also be presented at the upcoming National Meeting and Exhibition of the American Chemical Society in Salt Lake City, UT [2; 3].

Data published in PLoS ONE refer to two non peptidic and chemically unrelated MC4-receptor antagonists (tool compounds SNT207707 and SNT209858) that are orally active and cross the blood brain barrier. Both compounds were found to distinctly increase food intake in healthy mice. Moreover, in mice carrying a C26 adenocarcinoma repeated oral administration almost completely prevented the development of cachexia, i.e. significantly reduced tumor-induced weight loss, and showed beneficial effects on lean body mass and fat mass. In contrast to previously reported peptidic and small-molecule MC4-receptor antagonists, the compounds described here can be applied orally and, therefore, offer a considerable advantage for the treatment of cachexia patients.

Thomas Meier, Chief Scientific Officer of Santhera, said: "Treatment of Cancer Cachexia with MC4-receptor antagonists offers a promising therapy option for this severe and often deadly metabolic syndrome. The prevention of body weight loss in disease-relevant models and the distinct increase in food intake position this compound class as potential therapy for Cancer Cachexia. Over the last few months, we have achieved a breakthrough in efficacy and oral bioavailability with a new generation of compounds in two chemical families. Meanwhile, we have a strong back-up program for our lead compounds available and we are confident to select a clinical candidate in due course."

Santhera anticipates entering into the clinic with its lead compound in 2010. The Company has initiated partnering activities to build a strategic alliance for further development and commercialization of the program.

About cachexia syndrome and MC4-receptor antagonists

Cachexia (Greek for "poor condition") syndrome is one of the most debilitating and life-threatening aspects of cancer and other severe chronic illnesses. The syndrome is associated with anorexia (lack of appetite), fat and muscle tissue wasting, psychological distress and a progressively decreasing quality of life. Cachexia is characterized by major metabolic abnormalities and maladaptations such as reduced food and energy intake, increased resting energy expenditure and accelerated catabolism. Typically, the involuntary weight loss in excess of 5% in 12 months cannot be compensated for by increased food intake, which results in wasting of both adipose and skeletal muscle tissue and poor physical performance.

The exact nature of the underlying processes remains largely unknown, however, appetite regulating peptides, pro-inflammatory cytokines and other regulatory peptides are considered to be major factors. One pathway by which cytokines can induce anorexia is via an increase of pro-opiomelanocortin (POMC) gene expression in hypothalamic feeding circuits, leading to an enhanced production of α -melanocyte stimulating hormone (α -MSH), a strong inhibitor of appetite. The MC4-receptor in the hypothalamus is a crucial target in the pathway through which α -MSH exerts its appetite inhibiting effects. AgRP (agouti related protein) or small molecule MC4-receptor antagonists enhance food intake, reduce energy expenditure and catabolic activity. Accordingly, an interruption of this signaling pathway by means of MC4-receptor antagonists is seen as a promising treatment option for cachexia.

Cancer Cachexia affects about one million patients in the North America and Europe. Up to 80% of cancer patients suffer from the syndrome which accounts for approximately 20% of cancer deaths. Despite this high unmet medical need, no effective treatments are available. Currently used pharmacological interventions have limited utility or produce severe side-effects. The potential market size of the Cancer Cachexia market is estimated to be above USD 1 billion.

References

[1] Weyermann P, Dallmann R, Magyar J, Anklin C, Hufschmid M, et al. (2009) Orally Available Selective Melanocortin-4 Receptor Antagonists Stimulate Food Intake and Reduce Cancer-Induced Cachexia in Mice. PLoS ONE 4(3): e4774. doi:10.1371/journal.pone.0004774. March 2009, Volume 4, Issue 3, e4774.

[2] Soeberdt M. et al., Synthesis and evaluation of a novel, potent and selective, orally bioavailable melanocortin-4 receptor antagonist for the treatment of cancer cachexia (MEDI 068);

[3] Weyermann P. et al., Discovery and in vivo efficacy of a novel, selective, and orally bioavailable Melanocortin-4 receptor antagonist for the treatment of cancer cachexia (MEDI 090).

Both posters will be presented at the American Chemical Society's 237th National Meeting and Exhibition, March 22 to 26, 2009, Salt Lake City, UT.

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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®, has received marketing approval from Health Canada to treat Friedreich's Ataxia. The drug is investigated in two fully recruited pivotal trials in the United States and in Europe. The same compound 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.

For further information, contact

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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