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Santhera Obtains US and Canadian Patents for Use of Omigapil for the Treatment of Congenital Muscular Dystrophy

Liestal, Switzerland, February 8, 2011 – Santhera Pharmaceuticals (SIX: SANN) announced today, that the United States Patent and Trademark Office and the Canadian Intellectual Property Office granted patent protection for the use of omigapil for the treatment of Congenital Muscular Dystrophy until 2027 and 2026, respectively. These patent grants follow shortly after a similar positive decision was published by the European Patent Office. Congenital Muscular Dystrophy is a group of severe, genetically determined neuromuscular diseases frequently affecting infants or young children. No pharmacological therapy is currently available or in advanced clinical development to help people suffering from this life-threatening progressive muscle weakness.

The patent granted in Canada covers use of omigapil for the treatment or prevention of muscular dystrophy especially congenital muscular dystrophies resulting from laminin-alpha-2 deficiency as in the MDC1A form of Congenital Muscular Dystrophy. The granted US patent covers specifically the treatment or prevention of Ullrich congenital muscular dystrophy, Bethlem myopathy, or intermediate clinical manifestations. Orphan drug designation was granted to the program in 2008 by both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) providing market exclusivity for 7 and 10 years following marketing approval, respectively.

“The patents for omigapil in Congenital Muscular Dystrophy in the United States and Canada complement our strong IP protection for this development program”, commented Thomas Meier, Chief Scientific Officer of Santhera. “The US and Canadian patents further validate our in-house research and strengthens our product opportunities in the field of rare neuromuscular diseases.”

Santhera has completed the nonclinical development required for omigapil in support of a clinical study. This work was funded by a research grant from the French patient organization Association Française contre les Myopathies. The Company is seeking scientific advice from key opinion leaders in Congenital Muscular Dystrophy and will discuss the clinical development program with the FDA and EMA. The start of a Phase II/III program is anticipated for late 2011.

About Congenital Muscular Dystrophy

Congenital Muscular Dystrophy refers to a wide variety of inherited neuromuscular conditions characterized by different forms of progressive loss of muscle tissue. Severe forms can affect newborns or young children with life-threatening progressive muscle weakness (“*floppy infant syndrome*”).

Complications associated with the disorder cause immobility at young age and early mortality. Patients suffer from loss of body weight, skeletal deformations and respiratory distress resulting in immobility at young age and early mortality. A recent epidemiological estimate approximates a prevalence of 0.89 per 100,000. No pharmacological therapy is currently available or in advanced clinical development. Treatment options are confined to ventilatory support and orthopedic surgery for scoliosis as well as supplementary nutrition to avoid malnutrition.

Santhera focuses on distinct subtypes of Congenital Muscular Dystrophy caused by collagen-VI (Ullrich, Bethlem Myopathy) or laminin-alpha-2 (MDC1A) deficiency. Both subtypes are associated with mitochondrial dysfunction and muscle cell apoptosis. In vivo studies show that omigapil, an anti-apoptotic compound, inhibits cell death and reduces body weight loss and skeletal deformation while increasing locomotive activity and protecting from early mortality [1].

Reference

[1] Erb M. et.al. (2009). Omigapil ameliorates the pathology of muscle dystrophy caused by laminin-alpha-2 deficiency. Journal of Pharmacology and Experimental Therapeutics 331: 787-795

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative 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. For further information, please visit www.santhera.com.

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