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Santhera Receives US Patent for Fipamezole in the Treatment of Neurodegenerative Diseases

Liestal, Switzerland, March 19, 2014 – Santhera Pharmaceuticals (SIX: SANN) announced today that the United States Patent and Trademark Office has issued a Notice of Allowance for a Santhera patent which protects the use of the oromucosal administration route for fipamezole. The US patent 8,653,122, which provides an exclusivity period until 2027, is crucial for the commercial exploitation of fipamezole in the field of neurodegenerative diseases. Santhera has global rights to fipamezole and has previously published promising data of its Phase IIb clinical trial in the treatment of levodopa-induced dyskinesia in Parkinson's disease.

The US patent claims the use of fipamezole via the oromucosal route of administration, which is essentially the only method of administration that achieves sufficient plasma levels of the drug and that is suitable for long-term treatment. Santhera previously received notice of allowance for equivalent patents in the EU and most other important markets worldwide.

Thomas Meier, Chief Executive Officer of Santhera, commented: "This US patent now completes the patent protection estate for the fipamezole program and allows the commercial exploitation of fipamezole as potential treatment of neurodegenerative diseases, most notably of levodopa-induced dyskinesia in Parkinson's disease. As Santhera is mainly focusing on the registration of Raxone<sup>®</sup>/Catena<sup>®</sup> in Leber's Hereditary Optic Neuropathy, fipamezole is currently available for licensing."

**About Fipamezole** 

Fipamezole is an innovative and highly selective adrenergic alpha-2 receptor antagonist, perceived by clinicians to be one of the most promising drug candidates for the treatment of levodopa-induced dyskinesia in Parkinson's disease, the second most common and a severely debilitating neuro-degenerative disorder. Santhera demonstrated in a Phase IIb clinical trial that oromucosal fipamezole has the potential to safely and effectively reduce levodopa-induced dyskinesia and daily "off" time without exacerbation of parkinsonism [1].

[1] LeWitt P., et al (2012). Randomized clinical trial of fipamezole for dyskinesia in Parkinson disease (FJORD study). Neurology 79:163–169.

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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 orphan mitochondrial and neuromuscular diseases, such as Leber's Hereditary Optic Neuropathy, Duchenne Muscular Dystrophy and primary progressive Multiple Sclerosis, all of them areas of high unmet medical need with no current therapies.

For further information, please visit www.santhera.com.

Raxone® and Catena® are trademarks of Santhera Pharmaceuticals.

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