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# Santhera Anticipates Receiving a Negative CHMP Opinion on Appeal for Marketing Authorization Application for Raxone<sup>®</sup> in Duchenne Muscular Dystrophy

Liestal, Switzerland, January 24, 2018 – Santhera Pharmaceuticals (SIX: SANN) announces that on January 23 it had an oral explanation at the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in relation to the re-examination of its Marketing Authorization Application (MAA) for Raxone® (idebenone) in Duchenne muscular dystrophy (DMD). The company now anticipates that the CHMP will maintain its original position to issue a negative opinion on Santhera's MAA filed as Type II variation of its existing marketing authorization for Leber's hereditary optic neuropathy (LHON).

Santhera will provide further update on Friday, January 26, as originally announced.

### **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. Santhera's lead product Raxone® (idebenone) is authorized in the European Union, Norway, Iceland, Liechtenstein and Israel for the treatment of Leber's hereditary optic neuropathy (LHON). Santhera is currently conducting the Phase III SIDEROS trial with Raxone in patients with Duchenne muscular dystrophy in respiratory function decline. In collaboration with the U.S. National Institute of Neurological Disorders and Stroke (NINDS) Santhera is developing Raxone® in a third indication, primary progressive multiple sclerosis (PPMS), and another product – omigapil – for congenital muscular dystrophy (CMD), both also areas of high unmet medical need. For further information, please visit the Company's website www.santhera.com.

Raxone® is a trademark of Santhera Pharmaceuticals.

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