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Santhera launches Raxone® in its first EU market

Liestal, Switzerland, October 1, 2015 – Santhera Pharmaceuticals (SIX: SANN) announces that it is today launching Raxone® for the treatment of Leber's Hereditary Optic Neuropathy (LHON) in Germany, its first and largest EU market. LHON is a rare inherited mitochondrial disease that usually leads rapidly to profound and permanent blindness.

"The introduction of Raxone in Germany is a major step forward for LHON patients who now have an effective treatment option" said **Giovanni Stropoli**, Santhera's Chief Commercial Officer for Europe. "We are particularly proud as Raxone is also the first approved treatment for any mitochondrial disease, a therapeutic area which is in the focus of our Company. Germany is our first and largest EU market but product availability is anticipated in additional countries in the immediate future."

"Mitochondrial disease treatments have been elusive for a long time. The availability of Raxone for patients with LHON is changing the paradigm and also raises hopes for other mitochondrial disorders," said **Thomas Klopstock**, MD, Professor of Neurology at the University of Munich, LHON researcher and coordinator of the German network for mitochondrial disorders, mitoNET. "LHON patients usually become blind in young adulthood, which entails not only a personal and medical, but also a socioeconomic burden. With Raxone, we can now offer a treatment option which greatly improves the chances for significant recovery of visual acuity."

"As an organization representing the interests of patients affected with LHON, we are very excited that an approved medication is finally available for the treatment of this devastating disease," emphasized **Claus-Peter Eisenhardt**, President of the German Patient Advocacy of patients with mitochondrial diseases, within the German Society of Muscular Diseases (DGM). "We are grateful to the European regulatory authorities, who, after careful evaluation of all available data, approved Raxone and made LHON a treatable disease."

Raxone is an oral medication, authorized at a daily dose of 900 mg (given as 2 tablets three times a day with food), for the treatment of visual impairment in adolescent and adult patients with LHON. Treatment should be initiated and supervised by a physician with experience in LHON. Efficacy data come from Santhera's randomized, placebo-controlled RHODOS trial and from the open label Expanded Access Program, which together have demonstrated that vision loss can be mitigated or reversed in patients treated with Raxone.

About Leber's Hereditary Optic Neuropathy and the Therapeutic Use of Raxone

LHON is a heritable genetic disease causing blindness. The disease presents predominantly in young, otherwise healthy adult males as rapid, painless loss of central vision, usually leading to permanent bilateral blindness within a few months of the onset of symptoms. About 95% of patients harbor one of three pathogenic mutations of the mitochondrial DNA, which cause a defect in the complex I subunit of the mitochondrial respiratory chain. This defect leads to decreased cellular energy (ATP) production, increased reactive oxygen species (ROS) production and retinal ganglion cell dysfunction, which cause progressive loss of visual acuity and blindness.

Raxone (idebenone), a synthetic short-chain benzoquinone and a cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1), circumvents the complex I defect, reduces and scavenges ROS, restores cellular energy levels in retinal ganglion cells and promotes recovery of visual acuity.

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® is authorized in the European Union for the treatment of Leber's Hereditary Optic Neuropathy (LHON). Santhera is developing Raxone®/Catena® in two additional indications, Duchenne Muscular Dystrophy (DMD) and primary progressive Multiple Sclerosis (ppMS), and omigapil for Congenital Muscular Dystrophy (CMD), all areas of high unmet medical need. For further information, please visit the Company's website www.santhera.com.

Raxone® and Catena® are trademarks of Santhera Pharmaceuticals.

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