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Santhera Receives Rare Pediatric Disease Designation from FDA for Idebenone for the Treatment of Duchenne Muscular Dystrophy

Liestal, Switzerland, August 19, 2015 - Santhera Pharmaceuticals (SIX: SANN) announces that the U.S. Food and Drug Administration (FDA) has granted rare pediatric disease designation for Santhera's lead orphan drug candidate, idebenone, for the treatment of Duchenne Muscular Dystrophy (DMD). The rare pediatric disease designation supplements the orphan drug designation granted by the FDA for idebenone to treat DMD in February 2007.

"We are pleased that the FDA has granted our request to designate idebenone for the treatment of DMD as a drug for a rare pediatric disease," said **Thomas Meier**, PhD, Chief Executive Officer of Santhera. "We already have Fast Track designation for idebenone in DMD and, on this basis, will be requesting priority review when we file the planned NDA. The potential to obtain a Rare Pediatric Disease Priority Review Voucher from the FDA, which we could retain for a future clinical development program of our own or sell, could provide additional value for the company in the future."

About Rare Pediatric Disease Designation
The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily aged from birth to 18 years. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application (NDA) or biologics license application (BLA) for a rare pediatric disease may be eligible for a voucher which can be redeemed to obtain priority review for a subsequent marketing application for a different product. The Priority Review Voucher may be sold or transferred an unlimited number of times.

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 develops Raxone®/Catena® as treatment for patients with Leber's Hereditary Optic Neuropathy (LHON), Duchenne Muscular Dystrophy (DMD) and primary progressive Multiple Sclerosis (ppMS) and omigapil for Congenital Muscular Dystrophy (CMD), all areas of high unmet medical need. In June 2015, the Committee for Medicinal Products for Human Use (CHMP) recommended granting a marketing authorization in Europe for Raxone® for the treatment of LHON. For further information, please visit the Company's website www.santhera.com.

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