Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24, 4133 Pratteln, Switzerland
Phone: +41 61 906 89 50 | Fax: +41 61 906 89 51
www.santhera.com

Santhera's Licensing Partner, Nxera Pharma, Submits Marketing Authorization Application for AGAMREE® (Vamorolone) in South Korea

Pratteln, Switzerland, October 23, 2026 – Santhera Pharmaceuticals (SIX: SANN) today notes that its licensing partner Nxera Pharma Co., Ltd. ("Nxera") has submitted a Marketing Authorization Application (MAA) to South Korea's Ministry of Food and Drug Safety (MFDS) for AGAMREE (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD).

The submission follows the Orphan Drug Designation (ODD) and Global Innovative Products on Fast Track (GIFT) designation granted by the MFDS in June 2026. GIFT is a priority review pathway designed to accelerate the review of innovative medicines targeting life-threatening or serious diseases, including rare diseases, and is expected to help shorten the review timeline and support earlier patient access to vamorolone. Nxera is targeting marketing authorization in South Korea in 2027, followed by a commercial launch in 2028.

Nxera holds exclusive rights to AGAMREE for Japan, South Korea, Australia, and New Zealand under a licensing agreement signed in January 2026. Santhera will receive sales and milestone payments and royalties on net sales of AGAMREE in the licensed territories.

About Santhera
Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular diseases with high unmet medical need. The Company has an exclusive license from ReveraGen for all indications worldwide to AGAMREE® (vamorolone), a dissociative corticosteroid with a novel mode of action, which was investigated in a pivotal study in patients with Duchenne muscular dystrophy (DMD) as an alternative to standard corticosteroids. AGAMREE® for the treatment of DMD is approved in the U.S. by the Food and Drug Administration (FDA), in the EU by the European Commission (EC), in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), in Switzerland by Swissmedic, in China by the National Medical Products Administration (NMPA), in Hong Kong by the Department of Health (DoH) and in Canada by Health Canada. Santhera has out-licensed the rights to AGAMREE® as follows: to Catalyst Pharmaceuticals for North America; to Sperogenix Therapeutics for China and certain countries in Southeast Asia; and to Nxera Pharma for Japan, South Korea, Australia, and New Zealand. For further information, please visit www.santhera.com.

AGAMREE® is a trademark of Santhera Pharmaceuticals.

About Nxera Pharma
Nxera Pharma is a technology powered biopharma company in pursuit of new specialty medicines to improve the lives of patients with unmet needs in Japan and globally. The Company has built an agile, new-generation commercial business in Japan to develop and commercialize innovative medicines, including several launched products, to address this high-value, large and growing market and those in the broader APAC region. In addition, the Company is advancing an extensive pipeline internally and in partnership with leading pharma and biotech companies powered by its unique NxWave™ GPCR structure-based drug discovery platform. Nxera Pharma operates at key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea) and is listed on the Tokyo Stock Exchange (ticker: 4565).

For further information, please contact:

Santhera
Catherine Isted, Chief Financial Officer: IR@santhera.com
ICR Healthcare: Santhera@icrhealthcare.com

Stifel +44 (0)20 7710 7600
Brough Ransom, Charles Hoare, Fred Walsh

Octavian +41 (0)44 520 1588
Serge Monnerat, Marius Zuberbuehler

Disclaimer / Forward-looking statements
This communication does not constitute an offer or invitation to subscribe for or purchase any securities of Santhera Pharmaceuticals Holding AG. This publication may contain certain forward-looking statements concerning the Company and its business. Such statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the Company to be materially different from those expressed or implied by such statements. Readers should therefore not place undue reliance on these statements, particularly not in connection with any contract or investment decision. The Company disclaims any obligation to update these forward-looking statements.

##