

Ad hoc announcement pursuant to Art. 53 LR

Santhera Licenses AGAMREE® (Vamorolone) to Nxera Pharma in Japan, South Korea, Australia and New Zealand in a Deal Valued at up to USD 205 Million Plus Royalties

Exclusive licensing agreement includes USD 40 million upfront comprising USD 30 million in cash and USD 10 million equity investment at CHF 14.91 per share, a 20% premium to the 30-day VWAP.

Pratteln, Switzerland, January 8, 2026 – Santhera Pharmaceuticals (SIX: SANN) announces it has signed an exclusive licensing agreement with Nxera Pharma UK Ltd. (“Nxera”) for the development, manufacturing and commercialization of AGAMREE® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) in Japan, South Korea, Australia and New Zealand. Nxera is a leading international biopharma company with clinical development and commercial operations for rare and speciality medicines in Japan and the broader Asia-Pacific (APAC) region.

Under the terms of the agreement, Santhera will receive an upfront payment of USD 40 million from Nxera, consisting of USD 30 million in cash and USD 10 million as an equity investment in Santhera. The USD 10 million equity investment, through the purchase of c.530k shares, will be priced at CHF 14.91 per share, representing a 20% premium to the 30-day VWAP prior to the day of announcement. These shares will be issued shortly after closing of the agreement and will be subject to a customary lock up period. In addition, Santhera is eligible to receive up to USD 165 million in sales and regulatory milestone payments and will receive double-digit tiered royalties on net sales of AGAMREE in the licensed territories.

Nxera will be responsible for securing regulatory approval for AGAMREE in the licensed territories, including conducting a registrational bridging clinical study, and will lead on related commercial and manufacturing activities for the territories. This strategic partnership leverages Nxera's proven commercial capabilities and development and regulatory expertise across the APAC region, particularly in Japan, where there remains a significant unmet medical need for patients living with DMD. In addition to its expertise in developing and commercializing specialty care treatments, such as its lead product PIVLAZ™ (clazosentan), Nxera's team brings significant prior development and manufacturing experience with vamorolone through its 2023 acquisition of Idorsia's Japan and APAC business, with members of the former Idorsia (now Nxera) based team in Basel, having historically worked on the product in its earlier stages of development.

Dario Eklund, Chief Executive Officer of Santhera, commented: *“This strategic partnership represents a significant milestone in our mission to expand global access to AGAMREE and bring meaningful new treatment options to patients with DMD worldwide. Nxera's deep expertise and established infrastructure in Japan and across the wider APAC region, as well as prior experience of vamorolone, make them an ideal partner to unlock the full commercial and clinical potential of AGAMREE in these markets and accelerate access for patients with DMD.”*

Christopher Cargill, President and Chief Executive Officer of Nxera, added: *“We are excited to partner with Santhera to bring AGAMREE to DMD patients in Japan, South Korea, Australia and New Zealand. AGAMREE's differentiated safety and efficacy profile has the potential to fundamentally change the standard of care by enabling early use, full dosing, and long-term treatment, addressing critical limitations of existing steroid therapies currently used in the region.”*

About AGAMREE® (vamorolone)

AGAMREE is a novel drug with a mode of action based on binding to the same receptor as glucocorticoids but modifying its downstream activity. Moreover, it is not a substrate for the 11- β -hydroxysteroid dehydrogenase (11 β -HSD) enzymes that may be responsible for local drug amplification and corticosteroid-associated toxicity in local tissues [1-4]. This mechanism has shown the potential to 'dissociate' efficacy from steroid safety concerns and therefore AGAMREE is positioned as a dissociative anti-inflammatory drug and an alternative to existing corticosteroids, the current standard of care in children and adolescent patients with DMD [1-4].

In the pivotal VISION-DMD study, AGAMREE met the primary endpoint Time to Stand (TTSTAND) velocity versus placebo ($p=0.002$) at 24 weeks of treatment and showed a good safety and tolerability profile [1, 4]. The most commonly reported side effects were cushingoid features, vomiting, weight increase and irritability. Side effects were generally of mild to moderate severity.

Currently available data show that AGAMREE, unlike corticosteroids, has no restriction of growth [5] and no negative effects on bone metabolism as demonstrated by normal bone formation and bone resorption serum markers [6].

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

References:

- [1] Dang UJ et al. (2024) Neurology 2024;102:e208112. doi.org/10.1212/WNL.0000000000208112. [Link](#).
- [2] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. [Link](#).
- [3] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293
- [4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
- [5] Ward et al., WMS 2022, FP.27 - Poster 71. [Link](#).
- [6] Hasham et al., MDA 2022 Poster presentation. [Link](#).

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 steroid with 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 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 rights to AGAMREE for North America to Catalyst Pharmaceuticals and for China and certain countries in Southeast Asia to Sperogenix Therapeutics. 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, and powered by its unique NxWave™ GPCR structure-based drug discovery platform, the Company is advancing an extensive pipeline internally and in partnership with leading pharma and biotech companies. 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 more information, please visit www.nxera.life

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