Nxera Pharma Licenses Japan and Select Asia-Pacific Rights to Vamorolone for Duchenne Muscular Dystrophy from Santhera Pharmaceuticals

- Vamorolone is approved and marketed as AGAMREE® for the treatment of Duchenne Muscular Dystrophy (DMD) in the US, European Union, UK and China
- New five-year data on vamorolone highlighted substantially improved safety profile with reduced vertebral fractures, lower incidence of cataracts and that normal growth rate was maintained. With adverse effects being a key limitation of conventional corticosteroid therapy, vamorolone's safety profile combined its comparable effectiveness, has the potential to displace existing steroid treatments
- Transaction advances Nxera's mission to bring innovative medicines to patients in Japan/APAC in line with 2030 vision to build high-growth, highly profitable Japanese biopharma company

Tokyo, Japan and Cambridge, UK, 8 January 2026 – Nxera Pharma Co. Ltd ("Nxera" or "the Company; TSE 4565) today announces that it has entered an exclusive licensing agreement for the development, manufacturing and commercialization of vamorolone for the treatment of Duchenne Muscular Dystrophy (DMD) in Japan, South Korea, Australia and New Zealand with Santhera Pharmaceuticals Holding ("Santhera") (SIX: SANN). Vamorolone is approved and marketed as AGAMREE® for the treatment of DMD, a rare inherited neurodegenerative disease, in the US, European Union, UK and China.

The addition of vamorolone brings into Nxera's portfolio of innovative medicines for rare and specialty diseases, a late-stage development candidate with the potential to address significant unmet needs of patients in Japan and the Asia-Pacific ("APAC") region living with DMD. This portfolio includes PIVLAZ™ (clazosentan) and QUVIVIQ™ (daridorexant), both of which are approved and marketed in Japan and under commercial development in other APAC countries.

Under the terms of the agreement, Nxera will be responsible for obtaining regulatory approval of vamorolone in the licensed territories, including undertaking regulatory activities such as clinical trials where required, and will lead commercialization and manufacturing activities for those territories. This strategic partnership leverages Nxera's proven commercial capabilities and development and regulatory expertise across the APAC region, particularly in Japan. In addition, Nxera's team brings significant prior development and

manufacturing experience with vamorolone through its 2023 acquisition of Idorsia's Japan and APAC business.

Christopher Cargill, President and Chief Executive Officer of Nxera, commented: "We are excited to partner with Santhera to bring vamorolone to DMD patients in Japan, South Korea, Australia and New Zealand. Vamorolone'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.

"Furthermore, the transaction expands our portfolio of late- and commercial-stage products for Japan/APAC and advances our mission to bring innovative medicines to patients in these important regions in line with our 2030 vision to build high-growth, highly profitable Japanese biopharma company."

Dario Eklund, Chief Executive Officer of Santhera, added: "This strategic partnership represents a significant milestone in our mission to expand global access to AGAMREE® (vamorolone) 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® (vamorolone) in these markets and accelerate access for patients with DMD."

Additional transaction terms
In return for development, manufacturing and commercialization rights for vamorolone in the licensed territories, Nxera will make an upfront payment of USD 40 million to Santhera, consisting of USD 30 million in cash and USD 10 million as a strategic equity investment. Santhera is also eligible to receive sales and regulatory milestone payments of up to USD 165 million from Nxera as well as tiered royalties starting in the low teens on net sales of vamorolone in the licensed territories.

About Duchenne Muscular Dystrophy
Duchenne muscular dystrophy (DMD) is a rare inherited X-chromosome-linked disease, which almost exclusively affects males. DMD is characterized by inflammation which is present at birth or shortly thereafter. Inflammation leads to fibrosis of muscle and is clinically manifested by progressive muscle degeneration and weakness. Major milestones in the disease are the loss of ambulation, the loss of self-feeding, the start of assisted ventilation, and the development of cardiomyopathy. DMD reduces life expectancy to before the fourth decade due to respiratory and/or cardiac failure. Corticosteroids are the current standard of care for the treatment of DMD.

About vamorolone
Vamorolone 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 (11β-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 vamorolone 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, vamorolone 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. Five-year data from the GUARDIAN study

highlighted substantially improved safety profile with reduced vertebral fractures, lower incidence of cataracts and that normal growth rate was maintained.

Currently available data show that vamorolone, 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.

–END–

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
LinkedIn: @NxeraPharma | X: @NxeraPharma | YouTube: @NxeraPharma

QUVIVIQ™ is trademark of Idorsia Ltd.

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.

Enquiries:

For Nxera Pharma
Media and Investor Relations
Shinya Tsuzuki, VP, Head of Investor Relations
Maya Bennison, Communications Manager
+81 (0)3 5962 5718 | +44 (0)1223 949390 | IR@Nxera.life

MEDiSTRAVA (for International Media)
Mark Swallow, Frazer Hall, Erica Hollingsworth
+44 (0)203 928 6900 | Nxera@medistrava.com

For Santhera
Catherine Isted, Chief Financial Officer
IR@santhera.com

ICR Healthcare
Santhera@icrhealthcare.com

Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Nxera Pharma Group's actual results to differ materially from those expressed or implied by the forward looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.