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Santhera Announces Proposed Inclusion and Reimbursement of AGAMREE® (Vamorolone) within Spain's National Health System for the Treatment of Duchenne Muscular Dystrophy

Pratteln, Switzerland, February 27, 2026 – Santhera Pharmaceuticals (SIX: SANN) today announces that the Spanish Interministerial Commission on Prices of Medicines, has proposed to include AGAMREE® (vamorolone), in the pharmaceutical coverage of the Spanish National Health System, making it eligible for reimbursement.

The conditions for such inclusion will be determined in a resolution by the Directorate-General of Pharmacy at the Spanish Ministry of Health. The company expects to receive the draft of such resolution shortly. Once the company accepts the draft, the product will be included in the database of products financed by the National Health System in Spain. Assuming this process proceeds along typical timelines, Santhera plans to start to make the product available across the various regions in Spain from early in the second quarter of 2026.

Agamree® is a product approved by the European Commission for treating Duchenne muscular dystrophy in patients from 4 years of age. Duchenne muscular dystrophy is a genetic disease that gradually causes weakness and loss of muscle function. To date, AGAMREE has been available in Spain through a paid named-patient program since mid-2024.

Dario Eklund, Chief Executive Officer of Santhera, said: *"This positive announcement in Spain represents another important milestone in our mission to expand access to AGAMREE for patients with DMD in Europe and globally. This follows our commercial launches in Germany, Austria and the UK with a number of additional EU countries expected to follow during both the first and second halves of the year."*

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 (11β-HSD) enzymes that may be responsible for local drug amplification and corticosteroid-associated toxicity in local tissues [2-5]. 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 [2-5].

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 [2, 5]. 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 [6] and no negative effects on bone metabolism as demonstrated by normal bone formation and bone resorption serum markers [7].

▼ *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:

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[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 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.

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