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Santhera Announces Positive AIFA Board Decision on Reimbursement of AGAMREE® (vamorolone) in Italy

Pratteln, Switzerland, April 28, 2026 – Santhera Pharmaceuticals (SIX: SANN) announces that the Board of Directors of the Italian Medicines Agency, AIFA, has approved the reimbursement of AGAMREE® (vamorolone) for the treatment of patients with Duchenne muscular dystrophy (DMD) aged 4 years and older in Italy.

AGAMREE is a novel molecule designed to deliver the anti-inflammatory benefits typically associated with glucocorticoids while potentially reducing the risk of adverse effects linked to this class of therapies. DMD is a rare, progressive genetic disease characterized by muscle degeneration and reduced life expectancy due to respiratory and/or cardiac complications.

The reimbursement decision follows a positive evaluation by AIFA's Board of Directors on April 22, 2026. The determination is subject to formal publication in the Italian Official Gazette (Gazzetta Ufficiale), after which reimbursement will become effective.

Dario Eklund, Chief Executive Officer, said: *"This builds on our recent progress in Spain and reflects our continued momentum in expanding access to AGAMREE for patients with DMD. With four of the five major European markets expected to have access to AGAMREE in the near term, and supported by successful commercial launches in Germany, Austria and the UK, we are well positioned to sustain this momentum as we continue to broaden access to this important therapy*."

Santhera will provide further updates as appropriate following the official publication of the AIFA determination.

About AGAMREE® (vamorolone)
AGAMREE is a dissociative corticosteroid approved for the treatment of Duchenne muscular dystrophy (DMD). It binds selectively to the glucocorticoid receptor and triggers anti-inflammatory activity through inhibition of NF-κB-mediated gene transcription, while inducing reduced transactivation of other genes[1]. AGAMREE is not a substrate for 11-β-hydroxysteroid dehydrogenase (11β-HSD) enzymes, which are involved in the local amplification of glucocorticoid activity in tissues and have been implicated in corticosteroid-associated toxicity[2,3]. This pharmacological profile is the basis for its classification as a dissociative corticosteroid, designed to preserve anti-inflammatory efficacy while reducing the systemic effects associated with long-term conventional corticosteroid therapy[1–3].

In the pivotal Phase 2b VISION-DMD study, AGAMREE met its primary endpoint, demonstrating a statistically significant improvement in Time to Stand (TTSTAND) velocity versus placebo at 24 weeks ($p = 0.002$)[4]. The most commonly reported adverse reactions were cushingoid features, vomiting, weight increase, increased appetite, and irritability; most were mild to moderate in severity[1].

Long-term data from up to eight years of AGAMREE treatment were presented at the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in March 2026[5,6]. In propensity-matched analyses, AGAMREE demonstrated durable efficacy comparable to standard-of-care corticosteroids and a differentiated safety profile: a lower incidence of vertebral fractures versus deflazacort-treated cohorts (8.1% vs 41.9%; $p = 0.0082$)[5]; maintained normal growth trajectory with a mean height advantage of 12.17 cm versus conventional corticosteroids ($p < 0.0001$)[5,6], and a lower incidence of cataracts versus deflazacort ($p = 0.015$), with no observed cases of glaucoma[5].

▼ *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. AGAMREE (vamorolone) Summary of Product Characteristics. European Medicines Agency; authorised 14 December 2023. Link
2. Heier CR, Damsker JM, Yu Q, et al. VBP15, a novel anti-inflammatory and membrane-stabilizer, improves muscular dystrophy without side effects. Life Sci Alliance. 2019;2(1):e201800186. Link
3. Reeves EKM, Hoffman EP, Nagaraju K, et al. VBP15: preclinical characterization of a novel anti-inflammatory delta 9,11 steroid. Bioorg Med Chem. 2013;21(8):2241–2249. Link
4. Dang UJ, Damsker JM, Guglieri M, et al. Efficacy and safety of vamorolone over 48 weeks in boys with Duchenne muscular dystrophy (VISION-DMD). Neurology. 2024;102(5):e208112. Link
5. Guglieri M, et al. Long-term impact of vamorolone on bone health compared to standard of care glucocorticoids in boys with Duchenne muscular dystrophy. Poster 62S, MDA Clinical & Scientific Conference 2026. Link
6. McDonald CM, et al. Comparative analysis of long-term effectiveness of vamorolone versus standard of care glucocorticoid treatment in boys with Duchenne muscular dystrophy. Poster 23S, MDA Clinical & Scientific Conference 2026. 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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