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 Receives Swissmedic Approval of AGAMREE® (Vamorolone) for the Treatment of Duchenne Muscular Dystrophy

Commercial launch in Switzerland anticipated in H2 2026

Pratteln, Switzerland, January 15, 2026 – Santhera Pharmaceuticals (SIX: SANN) announces that the Swiss Agency for Therapeutic Products (Swissmedic), has approved AGAMREE® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older.

Dario Eklund, Chief Executive Officer of Santhera, commented*: "As a proudly Switzerland-based business, securing Swissmedic approval represents an important achievement, and marks our seventh global marketing approval. We expect to launch AGAMREE in Switzerland later in 2026, in order to ensure timely access to this important therapy for DMD patients in the country."*

The Swissmedic approval of AGAMREE was based on the data from the pivotal Phase 2b VISION-DMD study and assessment results from the European Medicines Agency. Following approval, the Company has been granted a 15-year exclusivity period under Swiss orphan drug status. Santhera retains exclusive distribution rights for AGAMREE in Switzerland and anticipates commercial launch in H2 2026, following the completion of national pricing and reimbursement procedures. There are over 200 people affected by DMD in Switzerland, with few treatment options available to them.

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 [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 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.

For further information please contact:

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

ICR Healthcare:
Santhera@icrhealthcare.com

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