

Santhera Secures Agreement with Uniphar for the Distribution of AGAMREE® (Vamorolone) in five GCC (Gulf Cooperation Council) Countries

Pratteln, Switzerland, 19 August, 2025 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive agreement with Uniphar to manage the distribution of AGAMREE® (vamorolone) in the United Arab Emirates, the Kingdom of Saudi Arabia, Kuwait, Oman and Bahrain, for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older.

Sales are expected to begin on a named patient basis in Q1 2026, with broader commercial sales anticipated in late 2026 following market authorization and pricing agreement. Santhera will receive a percentage of net sales as payment, consistent with the Company's previous distribution agreements. This agreement will help ensure that patients across these countries have timely access to this innovative therapy.

Dario Eklund, Chief Executive Officer of Santhera, said: "We are excited to partner with Uniphar for the distribution of AGAMREE in GCC (Gulf Cooperation Council) countries. Uniphar's strong regional presence, combined with its proven expertise in early and expanded access programs, will help address the significant unmet need for boys and men living with DMD in these countries. This agreement represents another important step in our global expansion strategy and demonstrates our unwavering commitment to making effective rare disease treatments accessible to patients worldwide."

Santhera remains committed to the global rollout of AGAMREE, which already includes multiple regions across North America, Europe and Asia, bringing this important therapy to patients with DMD who are in urgent need of treatment.

Brian O'Shaughnessy, Chief Commercial Officer of Uniphar said: "We are proud to collaborate with Santhera to bring AGAMREE to patients in GCC (Gulf Cooperation Council) countries. Our regional knowledge, commercial experience, and dedication to improving access to innovative therapies align perfectly with Santhera's mission. Together, we aim to ensure that patients living with DMD receive the treatment they need without delay."

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 Medicines Agency (EMA), in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), in China by the National Medical Products Administration (NMPA) and Hong Kong by the Department of Health (DoH). 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 Uniphar

Headquartered in Dublin, Ireland, Uniphar is a trusted global partner to pharma, medtech and biotech companies, working to improve patient access to medicines around the world. Uniphar's team of experts harness the capabilities, infrastructure and expertise of a diversified pharmaceutical service provider with more than 57 years' experience building success stories with 200+ multinational client across 180 countries worldwide.

Uniphar works across the entire pharmaceutical product lifecycle, providing integrated solutions that remove barriers to market entry, increase patient access, and optimize brand value. With a strong presence in Europe, North America, APAC, and MENA, Uniphar offers specialist services spanning early access programs, medical affairs, commercialisation, logistics, global sourcing and distribution. Its end-to-end model enables pharmaceutical companies to scale rapidly in complex markets while maintaining compliance and operational excellence.

The Company's vision is to improve patient access to pharmaco-medical products and treatments by enhancing connectivity between manufacturers and healthcare professionals and their patients, representing a strong combination of scale, growth, and profitability.

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