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# Santhera Secures Agreement with Biomedica for the Distribution of AGAMREE® (Vamorolone) in Russia

**Pratteln, Switzerland, October 9, 2025 –** Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive agreement with Biomedica for the distribution of AGAMREE® (vamorolone) in Russia, for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older.

Under the terms of the agreement, Santhera will receive a percentage of net sales, in line with previous distribution agreements, with sales expected to begin in Q1 2026. This collaboration will enable access to AGAMREE for DMD patients across the country, facilitated through regional and national managed access programs. There are approximately 1,400 patients living with DMD in Russia [1].

**Dario Eklund, Chief Executive Officer of Santhera, said:** "This agreement will enable more children to access this important DMD treatment, and is the latest in a series of global agreements secured in 2025. We look forward to working closely with Biomedica in the months ahead."

**Oleg Parosin, Founder and Chief Executive Officer of Biomedica added:** "Our deep expertise in neurology and DMD, particularly with therapies that complement AGAMREE, combined with our track record of successful partnerships with leading EU and US companies, positions us as a strong and trusted partner for Santhera in Russia. We look forward to working together to accelerate access and ensure the availability of AGAMREE from early next year, enabling even more patients to benefit from this essential therapy."

**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:
[1] Gordey Foundation
[2] Dang UJ et al. (2024) Neurology 2024;102:e208112. doi.org/10.1212/WNL.0000000000208112. Link.
[3] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480 Link.
[4] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293
[5] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
[6] Ward et al., WMS 2022, FP.27 - Poster 71. Link.
[7] 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 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.*

**About Biomedica**
Biomedica is a pharmaceutical company specializing in the commercialization of rare disease, innovative, and breakthrough therapies in underserved and emerging markets. With a strong presence across Central and Eastern Europe (CEE), the Commonwealth of Independent States (CIS), Turkey, and Israel, Biomedica partners with leading biotechnology and pharmaceutical innovators to bring novel treatments to patients. Its key therapeutic areas include rare diseases, neurology, haematology, oncology, hepatology and ophthalmology. Leveraging its regional expertise and established market access capabilities, Biomedica is committed to ensuring the timely access and availability of innovative therapies for patients with high unmet medical needs.

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