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# Santhera Enters into Agreement with Ikris Pharma Network for the Distribution of AGAMREE® (Vamorolone) in India

Pratteln, Switzerland, 29 August, 2025 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive agreement with Ikris Pharma Network (Ikris) to manage the distribution of AGAMREE® (vamorolone) in India, for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older.

The agreement between Santhera and Ikris has a 5-year term and Santhera will receive a percentage of net sales, in line with previous distribution agreements. Sales are expected to begin in Q4 2025 on a named patient basis.

Today's agreement follows recent distribution deals secured in Turkey and a range of Gulf Cooperation Council countries. Santhera continues to press ahead with the global rollout of AGAMREE.

**Dario Eklund, Chief Executive Officer of Santhera, said:** "We are pleased to partner with Ikris Pharma Network in India, which is part of our wider strategy to increase global access to AGAMREE for patients with DMD. Ikris has been actively working in the area of DMD and their expertise and dedication to ensuring rare disease drugs reach patients makes them an ideal partner in the region."

**Praveen Sikri, Founder & CEO of Ikris Pharma Network said:** "This collaboration with Santhera aligns with our focus of addressing unmet medical needs in the rare disease community. We look forward to leveraging our distribution network to help DMD patients in India access this life-changing treatment."

## 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- $\beta$ -hydroxysteroid dehydrogenase ( $11\beta$ -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.

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#### 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 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 <a href="https://www.santhera.com">www.santhera.com</a>.

AGAMREE® is a trademark of Santhera Pharmaceuticals.

### **About Ikris Pharma Network**

Ikris Pharma Network is India's biggest named patient supply company, specializing in providing access to rare disease medications. With established expertise in logistics, regulatory compliance, and patient access programs, Ikris has supported physicians and patients in obtaining therapies that are not locally available. The company has been actively working in the area of Duchenne muscular dystrophy (DMD), providing assistance to patients and healthcare professionals in India.

# Partnership Impact:

Through its authorization with Santhera Pharmaceuticals, Ikris Pharma Network will facilitate access to AGAMREE® (vamorolone) for eligible patients with Duchenne Muscular Dystrophy in India. The collaboration aims to provide a regulatory-compliant pathway for access and strengthen existing efforts in patient support and disease awareness in the country.

## **Duchenne Muscular Dystrophy (DMD):**

DMD is a rare genetic disorder caused by mutations in the dystrophin gene, leading to progressive muscle weakness that usually begins in early childhood. Most patients lose ambulation in adolescence. While there is no cure, available treatments such as corticosteroids and supportive care can help manage symptoms. Expanding access to therapies like AGAMREE is intended to support the ongoing care of patients and families living with DMD in India.

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**Ikris Pharma Network** 

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# **Disclaimer / Forward-looking statements**

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