

## **Santhera Enters into Supply and Distribution Agreement for AGAMREE® (Vamorolone) with Clinigen Group**

**Pratteln, Switzerland, January 6, 2025 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive agreement with Clinigen Group to manage the supply and distribution of AGAMREE® (vamorolone) in countries where the product is not otherwise commercially available.**

Santhera Pharmaceuticals and Clinigen Group announce that they have signed a Supply and Distribution Agreement for AGAMREE in countries where the product can currently not be commercially obtained via Santhera or one of its current distribution partners. The agreement will enable access to AGAMREE on a case-by-case basis for patients with Duchenne muscular dystrophy (DMD) in situations where the treating physician deems there to be no suitable alternatives and where regulations allow for it. This agreement allows Santhera to receive the majority share of revenue generated from the supply of product in these additional countries.

“This distribution agreement with Clinigen, which is complementary to other, earlier announced, partnerships and agreements, will allow Santhera to significantly increase our service level to patients and healthcare professionals through processing individual requests for AGAMREE from geographies in which Santhera is not directly represented or while negotiations with local partners are ongoing,” said **Geert Jan van Daal, MD, PhD, Chief Commercial Officer of Santhera.**

“DMD is one of the most common and devastating types of muscular degeneration, it is a progressive condition diagnosed in childhood and it is encouraging to be able to help healthcare professionals support appropriate patients with an additional treatment option. We look forward to working with Santhera to make AGAMREE available to patients globally on an unlicensed basis in those territories where it is not currently licensed or reimbursed. This partnership demonstrates our ongoing commitment to accelerate access to medicines, to improve the quality of people’s lives around the world,” said **Julie Gosper, Senior Vice President, Europe and Partner Markets at Clinigen.**

In addition to opening this distribution channel, Santhera continues its gradual rollout of AGAMREE in key European geographies. Commercialization of AGAMREE in Germany and Austria, where the reception has been very positive, started in Q1-2024. Santhera plans to launch AGAMREE in Europe's other major markets, with the UK (including Scotland) in early 2025. The rollout will continue throughout 2025 across France, Italy, Spain, and other European countries. Santhera continues to expand its partner network, which already includes multiple geographies, to bring AGAMREE to patients with DMD in need of treatment.

### **About AGAMREE® (vamorolone)**

AGAMREE (vamorolone), an orphan medicinal product, is approved for use in the United States ([Prescribing Information](#)), the European Union ([Summary of Product Characteristics](#)), the United Kingdom, Mainland China and Hong Kong.

#### 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 Duchenne Muscular Dystrophy**

Duchenne muscular dystrophy (DMD) is a rare inherited X-chromosome-linked disease, which almost exclusively affects males. DMD is characterized by inflammation which is present at birth or shortly thereafter. Inflammation leads to fibrosis of muscle and is clinically manifested by progressive muscle degeneration and weakness. Major milestones in the disease are the loss of ambulation, the loss of self-feeding, the start of assisted ventilation, and the development of cardiomyopathy. DMD reduces life expectancy to before the fourth decade due to respiratory and/or cardiac failure. Corticosteroids are the current standard of care for the treatment of DMD.

### **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](http://www.santhera.com).

*AGAMREE® is a trademark of Santhera Pharmaceuticals.*

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### **About Clinigen**

Clinigen is a global, specialist pharmaceutical services company focused on providing ethical access to medicines. Its mission is to accelerate access to medicines for patients in every corner of the globe. The Group supports pharmaceutical and biotech companies across the medical product lifecycle, from clinical through to commercial and operates from sites in North America, Europe, Africa and the Asia Pacific. Clinigen has more than 1,100 employees across five continents in 15 countries and provides access in more than 130 countries every year. For more information on Clinigen, please visit <http://www.clinigen.com>.

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