

## **Santhera Enters into Exclusive Supply Agreement for AGAMREE® (Vamorolone) with Ali Al Suwaidi Trading Establishment (ASTE) in Qatar**

**Pratteln, Switzerland, November 12, 2024 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive supply agreement with Ali Al Suwaidi Trading Est. (ASTE) for the treatment of patients with Duchenne muscular dystrophy (DMD) with AGAMREE under a Named Patient Program.**

The agreement enables ASTE, a pioneering healthcare distributor with over four decades of experience in Qatar, to address the high unmet need of DMD patients in the region. As the sole distributor of AGAMREE to Qatari health institutions, ASTE will collaborate with Santhera to facilitate the management of patients under the Named Patient Program.

“This distribution agreement with ASTE marks another significant milestone for Santhera as we expand the global availability of AGAMREE. By partnering with expert organizations that have a strong understanding of specialist markets, we ensure optimal patient access,” said **Geert Jan van Daal, MD, PhD, Chief Commercial Officer of Santhera**. “This collaboration represents our first step into another important geographical region, advancing our mission to make AGAMREE available to Duchenne patients across the globe.”

“As a longstanding distributor in Qatar's healthcare sector, we are proud to partner with Santhera to facilitate the access of this innovative treatment to patients with Duchenne muscular dystrophy,” said **Ali Mohamed Al-Suwaidi, Chairman of Ali Al Suwaidi Trading Est.** “With our extensive experience in specialty pharmaceutical distribution and established relationships with healthcare institutions across Qatar, we are well-positioned to ensure AGAMREE reaches the patients who need it most. This collaboration aligns perfectly with our mission to deliver innovative healthcare solutions to the Qatari market.”

### **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].

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

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 and pulmonary 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), and in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA). Santhera has out-licensed rights to vamorolone for North America to Catalyst Pharmaceuticals and for China to Sperogenix Therapeutics. For further information, please visit [www.santhera.com](http://www.santhera.com).

*AGAMREE® is a trademark of Santhera Pharmaceuticals.*

### **About Ali Al Suwaidi Trading Est (ASTE)**

ASTE is one of the leading distributors in Qatar with a history of 42 years in the industry. It is a Qatari-owned company, serving the healthcare sector through pharmaceuticals, medical and laboratory equipment distribution. Through selective partnerships, ASTE strives to identify latent needs and offer the most innovative and efficient products and services to efficiently cater to the healthcare system. Its vision is to be the trusted partner in healthcare and life sciences solutions, driving positive outcomes and consistently improving people's well-being. ASTE invariably seeks to contribute to the development of the healthcare sector in the region and to continue to empower lives through innovative healthcare solutions.

**For further information please contact:**

[public-relations@santhera.com](mailto:public-relations@santhera.com) or

Andrew Smith, Chief Financial Officer

[andrew.smith@santhera.com](mailto:andrew.smith@santhera.com)

**Disclaimer / Forward-looking**

This communication does not constitute an offer or invitation to subscribe for or purchase any securities of Santhera Pharmaceuticals Holding AG. This publication may contain certain forward-looking statements concerning the Company and its business. Such statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the Company to be materially different from those expressed or implied by such statements. Readers should therefore not place undue reliance on these statements, particularly not in connection with any contract or investment decision. The Company disclaims any obligation to update these forward-looking statements.

###