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Ad hoc announcement pursuant to Art. 53 LR

Santhera Announces Agreement with German GKV-SV on Reimbursement Amount for AGAMREE® (vamorolone) for the Treatment of Duchenne Muscular Dystrophy in Germany

- *AGAMREE® is the first product to receive an agreed federal price in Germany for the treatment of all DMD patients 4 years and older, and independent of genetic mutation*

Pratteln, Switzerland, February 13, 2025 – Santhera Pharmaceuticals (SIX: SANN), a specialty pharmaceutical company focused on rare diseases, today announces an agreement with the German National Association of Statutory Health Insurance Funds (GKV-SV) on the reimbursement for AGAMREE® (vamorolone) for the treatment of Duchenne Muscular Dystrophy (DMD). This milestone makes AGAMREE the first product to receive an agreed federal price in Germany for the treatment of DMD in patients 4 years of age and older, independent of the underlying genetic mutation.

The agreement secured with the GKV-SV reflects Santhera's commitment to ensuring broad patient access while supporting sustainable healthcare outcomes. The agreed ex-factory price is EUR 3,612.50 per 100ml bottle, translating into approximately EUR 52,000 per year for an average patient when considering required rebates, patient weight and dosing.

"We are pleased to have reached an agreement on the reimbursement for AGAMREE with the GKV-SV, which provides health insurance coverage for approximately 90% of the German population," said **Dario Eklund, CEO of Santhera**. "This agreement represents an important step in providing access to AGAMREE for boys and men living with DMD in Germany and underscores our dedication to addressing the needs of the rare disease community."

Since its launch in Germany in January 2024, there are now more than 300 patients on continuing treatment with AGAMREE, representing almost 30% of those currently on steroid treatment. This is a significant achievement given the pivotal study of vamorolone did not include any German trial sites. Germany has 2,300 individuals living with DMD, of whom approximately 1,100 to 1,200 are treated with steroids at any one time. This highlights the potential for broader adoption and the positive impact of this reimbursement agreement.

Santhera remains committed to working closely with healthcare providers, patient organizations, and payers to support access to AGAMREE for all eligible boys and men with DMD. This agreement ensures that patients across Germany can benefit from this innovative therapy, enhancing the quality of care and outcomes for those affected by DMD.

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].

▼ *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 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.

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