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Santhera Secures Agreement with GEN for the Distribution of AGAMREE® (Vamorolone) in Türkiye

Pratteln, Switzerland, 13 August, 2025 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive agreement with Gen İlaç ve Sağlık Ürünleri San. ve Tic. A.Ş. (GEN) for the distribution and promotion of AGAMREE® (vamorolone) in Türkiye for the treatment of Duchenne muscular dystrophy (DMD) in patients four years of age and older.

Supply and sales by GEN are expected to start in the first half of 2026, initially on a named patient basis, followed by commercial sales. Santhera has received a small upfront payment and, as per previous agreements, will receive an ongoing percentage of net sales.

Dario Eklund, Chief Executive Officer of Santhera, said: "As leaders in the Turkish specialty pharmaceuticals market, GEN were a natural choice for Santhera as we looked for a high-quality distribution partner. We look forward to working closely in the run up to launching in the country in 2026, to provide access to the many DMD patients lacking suitable treatment options."

Abidin Gülmüş, Chairman/CEO of GEN, added: "The potential for AGAMREE is clear, and we are determined to ensure this DMD therapy reaches patients in Türkiye without delay. We understand the rare disease market deeply, use our longtime experience on neuromuscular diseases and look forward to partnering with Santhera in the months and years ahead."

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 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.

AGAMREE® is a trademark of Santhera Pharmaceuticals.

About GEN

Gen İlaç ve Sağlık Ürünleri San. Ve Tic. A.Ş. (BIST: GENIL.IS) is Türkiye's leading specialty pharmaceutical company, focused on developing innovative therapies across multiple therapeutic areas including neurological and neuromuscular disorders (DMD, SMA, etc) since 1998. GEN manufactures high-quality, competitive products at its GMP-certified facility and pursues original drug development through two dedicated R&D centers and investments. For further information, please visit www.genilac.com.tr

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