Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24, 4133 Pratteln, Switzerland

Phone: +41 61 906 89 50 | Fax: +41 61 906 89 51
www.santhera.com

Santhera Enters into an Exclusive Distribution Agreement with GENESIS Pharma for AGAMREE® (Vamorolone) in Central and Eastern Europe

Pratteln, Switzerland, September 10, 2024 – Santhera Pharmaceuticals (SIX: SANN) announces the signing of an exclusive distribution agreement with GENESIS Pharma for AGAMREE® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) in 20 markets in Central and Eastern Europe.

Santhera Pharmaceuticals and GENESIS Pharma have signed a distribution agreement for 20 markets in Central and Eastern Europe. This strategic collaboration aims to address unmet medical needs by allowing GENESIS Pharma to commercialize AGAMREE in Greece, Cyprus, Malta, Romania, Bulgaria, Slovenia, Croatia, Poland, Czech Republic, Hungary, Slovakia, Lithuania, Latvia, Estonia, Serbia, North Macedonia, Bosnia & Herzegovina, Montenegro, Albania, and Kosovo.

"This distribution agreement with GENESIS Pharma marks a significant achievement for Santhera as we expand the global availability of AGAMREE. By partnering with expert organizations with a strong understanding of specialist markets, we ensure optimal patient access," said **Geert Jan van Daal, MD, PhD, Chief Commercial Officer of Santhera**. "This is a further step in our strategy to allow focus on key European markets with dedicated Santhera teams while partnering with the best companies for non-core European markets."

Constantinos Evripides, Managing Director of GENESIS Pharma, stated: "Our company has a strong focus on rare diseases and an established expertise of more than twenty years in the commercialization of orphan therapies. We are delighted that Santhera has trusted our capabilities across the CEE region, giving us the opportunity to add Vamorolone to our broad and robust orphans' portfolio. We will work closely and diligently with Santhera to ensure a smooth and unhindered access to all patients that can benefit from this innovative treatment."

The European Commission approved AGAMREE for the treatment of DMD, in patients 4 years of age and older, in December 2023. This was based on data from the positive pivotal DMD study and three open-label studies. Patients treated with AGAMREE or placebo showed normal and similar growth while growth stunting was observed in children treated with prednisone. In addition, patients who switched from a standard of care corticosteroid to AGAMREE maintained the efficacy benefit while recovering their growth and bone health.

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.

AGAMREE® is a trademark of Santhera Pharmaceuticals.

About GENESIS Pharma

GENESIS Pharma is a regional biopharma company focused on the commercialization of innovative biopharmaceutical products targeting severe and rare diseases in Central and Eastern Europe. Established in 1997, GENESIS Pharma was among the first pharmaceutical companies in Europe to specialize in the marketing, sales and distribution of biopharmaceutical products. GENESIS Pharma

maintains a strong portfolio in therapeutic areas with high unmet medical need through long standing strategic alliances with some of the leading global biopharma companies. For more information, please visit www.genesispharmagroup.com.

For further information please contact:
public-relations@santhera.com or
Eva Kalias, Head Investor Relations & Communications
Phone: +41 79 875 27 80
eva.kalias@santhera.com

For more information about GENESIS Pharma, please contact:
Natalia Karahaliou, Communications Manager
nkarahaliou@genesispharma.com
Phone: +30 210 87 71 605

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