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Ad hoc announcement pursuant to Art. 53 LR

A conference call will be held today at 14:30 CEST / 13:30 BST / 08:30 EDT. Details are at the end of this news release.

Santhera Grants Exclusive North America License for Vamorolone to Catalyst Pharmaceuticals in Deal Valued at up to USD 231 Million Plus Royalties

- **Santhera will receive USD 90 million upfront at closing (USD 75 million in cash and USD 15 million equity investment), an additional USD 10 million upon U.S. FDA approval of vamorolone in Duchenne muscular dystrophy (DMD) plus USD 26 million to pay approval related regulatory milestones to third parties, and potential sales milestones of up to USD 105 million**
- **Agreement covers commercialization of vamorolone in DMD and rights to all potential future indications in North America (NA)**
- **Catalyst will pay Santhera up to low-teen percentage royalties and will assume corresponding third-party royalty obligations on vamorolone sales in NA**
- **Santhera will continue to focus on European commercialization of vamorolone in DMD, and further development of its clinical pipeline**
- **Santhera and Catalyst intend to collaborate on joint clinical development and funding of vamorolone for additional indications beyond DMD**
- **Proceeds allow for repayment of all short-term debt with Highbridge and an overall strengthening of the balance sheet**

Pratteln, Switzerland, June 20, 2023 – Santhera Pharmaceuticals (SIX: SANN) announces that it has signed an exclusive license and collaboration agreement for vamorolone in North America (NA) with Catalyst Pharmaceuticals, Inc. (NASDAQ: CPRX), a commercial-stage biopharmaceutical company focused on novel medicines for patients living with rare diseases. Total consideration to Santhera is up to USD 231 million (including equity investment), plus royalty payments from product sales, with near-term cash proceeds for Santhera of USD 126 million.

Under the terms of the agreement, Santhera will grant Catalyst exclusive commercialization rights to vamorolone in North America, comprising the U.S., Canada and Mexico. At closing, Santhera will receive an upfront cash payment of USD 75 million. In addition, Catalyst will make an equity investment of USD 15 million through the purchase of 14,146,882 treasury shares at a price of CHF 0.9477 per share which corresponds to the ten-day volume-weighted average price ending two days prior to signing of the agreement, subject to a six-month post-closing lock-up and standstill. Use of proceeds from the equity investment will support Phase 4 studies in DMD and joint development of additional indications. Upon U.S. FDA approval of vamorolone in DMD, a decision expected on October 26, 2023 (PDUFA date), Santhera would receive an additional USD 36 million from Catalyst, of which Santhera would pay contractually agreed third-party regulatory milestone obligations (USD 26 million). Furthermore, Catalyst

may pay Santhera sales-based milestones of up to USD 105 million as well as up to low-teen percentage royalties and will assume corresponding third-party royalty obligations of Santhera on vamorolone sales in all indications in NA.

Dario Eklund, Chief Executive Officer of Santhera, commented: "Duchenne muscular dystrophy is a devastating condition. Everyone at Santhera has been working diligently to advance vamorolone in order to make this important treatment option available to patients. We believe Catalyst is well placed to maximize the value of vamorolone and, subject to regulatory approval, ensure patients in North America receive this transformational therapy as quickly as possible. Catalyst has a track record of success in the rare disease and neuromuscular space and is our commercial partner of choice for North America with an established infrastructure and commitment to patients. With our new partner, we also look forward to jointly address the benefits of vamorolone in additional indications. As part of this agreement, Santhera benefits from upfront, milestone and royalty payments which allows us to focus on the commercial roll-out of vamorolone in DMD and future other indications in Europe."

In Europe, Santhera plans to commercialize vamorolone in key geographies (including Germany, France, UK, Italy, Spain, Benelux), and will seek partners for commercialization in all other countries. Market access, the build-up of a core organization and stakeholder engagement activities in these priority countries are ongoing. Already ahead of the European approval decisions expected at year-end, the early access programs submitted in the UK and France could allow treatment of first DMD patients with vamorolone. For certain countries, where Santhera chooses not to market vamorolone directly, including certain European countries and Japan, it has granted Catalyst a right of first negotiation in partnering discussions.

The new drug application (NDA) for vamorolone in DMD is under review in the U.S. by FDA, which has set October 26, 2023 as the Prescription Drug User Fee Act (PDUFA) date for its regulatory decision on approval. In Europe, the review of the marketing authorization application (MAA) for vamorolone by the European Medicines Agency (EMA) is ongoing. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in Q3-2023, followed by an approval decision by the European Commission (EC) in late 2023. In the UK, a corresponding MAA is under review by the Medicines and Healthcare products Regulatory Agency (MHRA). Subject to approvals, vamorolone could be launched in both the first EU countries and the U.S. in late 2023 and early in the first quarter 2024, respectively.

For indications in addition to DMD, Santhera and Catalyst will establish a joint steering committee (JSC) to undertake the joint clinical development of vamorolone for global indications, in which both parties would participate in the development process and funding.

The closing of the transaction is expected to occur early in the third quarter 2023, subject to customary conditions and regulatory clearances in the United States.

Funding Outlook

The near-term proceeds from the agreement with Catalyst amount to USD 100 million (cash inflows of USD 126 million net of regulatory approval milestone obligation to third parties of USD 26 million). This substantial infusion of funds significantly extends the Company's cash reach into Q1-2025, providing a strong financial foundation for future endeavors including advancing development of vamorolone and European commercialization. In addition, funds will also be allocated towards the repayment of the

exchangeable notes facility to Highbridge, resulting in a substantial reduction in debt and strengthening the Company's financial position.

Advisors
Centerview Partners and H.C. Wainwright & Co. acted as financial advisors to Santhera.

Conference Call
Santhera will host a conference call on June 20, 2023, at 14:30 CEST / 13:30 BST / 08:30 EDT to discuss the agreement on vamorolone. Participants are invited to call one of the following numbers (no dial-in code is required):

Switzerland/Europe: +41 58 310 50 00
United Kingdom: +44 207 107 06 13
USA: +1 631 570 56 13

A replay will be accessible at https://www.santhera.com/ad-hoc-news from about two hours after the call has ended.

About Vamorolone
Vamorolone is an investigational drug candidate with a mode of action based on binding to the same receptor as glucocorticoids but modifying its downstream activity and as such is considered a dissociative anti-inflammatory drug [2-5]. This mechanism has shown the potential to 'dissociate' efficacy from steroid safety concerns and therefore vamorolone could emerge as an alternative to existing corticosteroids, the current standard of care in children and adolescent subjects with DMD. In the pivotal VISION-DMD study, vamorolone 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]. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

Vamorolone has been granted Orphan Drug status for DMD in the U.S. and in Europe and has received Fast Track and Rare Pediatric Disease designations by the U.S. FDA and Promising Innovative Medicine (PIM) status from the UK MHRA for DMD. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

References:
[1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. Link.
[2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. Link.
[3] Guglieri M et al (2022) JAMA. doi:10.1001/jama.2022.4315
[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
[5] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293

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 Catalyst Pharmaceuticals

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases. Catalyst's flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") for adults and for children ages six and up. In January 2023, Catalyst acquired the U.S. commercial rights to FYCOMPA® (perampanel) CIII, a prescription medicine approved in people with epilepsy aged four and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older. Further, Canada's national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE® for the treatment of adult patients in Canada with LEMS. For additional information about the Company, please visit www.catalystpharma.com.

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 for all indications worldwide to 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. For vamorolone in the treatment of DMD, Santhera has a new drug application (NDA) under review by the U.S. FDA, a marketing authorization application (MAA) under review by the European Medicines Agency (EMA) and an MAA submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA). The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group. For further information, please visit www.santhera.com.

Raxone® is a trademark of Santhera Pharmaceuticals.

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