Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24, 4133 Pratteln, Switzerland

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

Ad hoc announcement pursuant to Art. 53 LR

Santhera Concludes Agreement with French Authorities on Raxone® Reimbursement and Plans to Submit a Request for an Early Access Program for Vamorolone

Pratteln, Switzerland, February 8, 2023 – Santhera Pharmaceuticals (SIX: SANN) announces that it has secured a final reimbursement agreement with the French authorities related to Raxone® (idebenone) for the treatment of Leber's hereditary optic neuropathy (LHON) and sales are expected to resume shortly. In addition, the Company plans to submit a request in France in the near-term for an early access program for vamorolone for the treatment of Duchenne muscular dystrophy (DMD).

Since its introduction in 2015, Raxone was available to patients in France for the treatment of LHON and reimbursed under a temporary financing scheme (formerly known as ATU). From August 2021, after the French authorities challenged the temporary pricing and removed Raxone from the list of reimbursed drugs under an ATU, Santhera has supplied LHON patients with Raxone free of charge in order to secure uninterrupted access. Reimbursement discussions have now concluded with an agreement on Raxone pricing. Shortly, Raxone will be on the list of reimbursed products in France, and Santhera can resume generating sales.

The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment, as announced earlier. Santhera will make repayments in the total amount of approximately EUR 25 million, with 30% due around mid-2024 and the remainder one year later. The Company has already made accruals for such payments and published these in the interim results for the period to June 30, 2022. The first payment is currently expected to be covered by sales generated until mid-2024, while the majority of the second payment will be covered by sales beyond mid-2025. Outside of France and North America, Santhera has outlicensed Raxone to Chiesi Group.

“We are glad to have reached an agreement with the French authorities on the matter of Raxone reimbursement. Most importantly, we are very pleased that we have succeeded in maintaining access to therapeutic care by providing Raxone without any interruption to patients suffering from this devastating disease,” said **Dario Eklund, CEO of Santhera.** “This settlement now enables us to progress discussions on completing outlicensing of Raxone which are further supported by encouraging clinical data with Raxone from studies completed in the recent past. Meanwhile, we remain fully focused on advancing our lead candidate vamorolone for DMD towards approval and market entry in the U.S. and the EU in late 2023 earliest.”

Santhera plans to submit a request for a vamorolone early access program (AAP, autorisation d'accès précoce) in France. Once approved, this program would enable early availability of vamorolone to patients and could generate product sales in France in the second half of 2023, ahead of an approval by the European Medicines Agency (EMA).

Earlier in January, Santhera announced FDA acceptance of the new drug application (NDA) for vamorolone for DMD for filing. Subject to approval, Santhera plans to launch vamorolone in the U.S. in Q4-2023. European marketing authorization application (MAA) for vamorolone has been validated and is under review by the EMA which could pave the way for a first EU launch in late 2023.

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. Santhera has a new drug application (NDA) under review by the U.S. FDA and a marketing authorization application (MAA) under review by the European Medicines Agency (EMA) for vamorolone for the treatment of DMD. 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.

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

Disclaimer / Forward-looking statements

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.

# # #