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.

Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The Company is planning for filing for approval with the US FDA in Q1-2022. 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 the Company's website www.santhera.com

Come and join our team to contribute to providing treatment options for patients with rare diseases that have a severe impact on the lives of affected children and adults. You can make a difference as:

Clinical Pharmacology Lead

at our Headquarters in Pratteln, Switzerland (close to Basel) on a full-time basis.

Scope of Work

The **Clinical Pharmacology Lead** will be part of the Clinical Science team and is responsible for developing and implementing the Clinical Pharmacology Plan and Modeling-Informed Drug Development strategies for early stage drug development programs, using state-of-the-art quantitative methodologies to integrate knowledge of biology, pharmacology, pharmacokinetics (PK), pharmacodynamics (PD), modelling and simulation.

The core responsibilities are:

- Help develop clinical pharmacology plan for early stage drug development programs, including both small and large molecules.
- Act as clinical pharmacology subject matter expert on multidisciplinary teams working closely with clinicians, biostatisticians, and clinical operations colleagues to design, conduct and report clinical trials from first-in-human to proof-of-concept; responsible for clinical pharmacology components including PK, PK/PD, food effect (oral compound), drug-drug interaction, QTc, and immunogenicity (biologics).
- Collaborate with preclinical scientists and critically evaluate translational models developed from preclinical data to ensure adequate confidence in prediction of human PK and efficacious dose projections.
- Provide scientific justification for optimal human starting dose and dose escalation schemes for first-in-human protocols based on all available preclinical information including toxicology, efficacy models, physicochemical and biochemical characterization.
- Work closely with clinical assay specialists to ensure that appropriate and validated bioanalytical assays are available on time for measuring drug concentration and anti-drug antibodies (for biologics) for clinical studies.
- Lead the conduct of PK data analysis and the development of computational models from PK/PD, safety and efficacy data collected in early stage clinical trials to support key program decision-making.
- Present clinical pharmacology results to internal and external stakeholders.

- Author clinical pharmacology components of clinical documents including protocols, investigator brochures, clinical development plans, study reports and regulatory modules; author scientific publications.

Required background and experience:

- Advanced degree (Ph.D., Pharm.D.) or equivalent experience in Pharmacokinetics, Pharmacometrics, Pharmaceutical Sciences, Engineering, Systems Biology or other related disciplines.
- Additional expertise in PK data analysis and PKPD model development is a plus.
- At least 5 years of industry or equivalent experience in clinical pharmacology and/or clinical PK/PD and/or pharmacometrics.
- Demonstrated ability to work in a highly collaborative, multi-disciplinary team setting.
- Excellent verbal and written communication skills.
- Self-directed and highly-motivated researcher, with willingness to learning new tools and approaches.

Required competencies:

- Previous experience in leading clinical pharmacology development plans, from first in human to Phase 3.
- Previous experience in writing pharmacology sections of regulatory documents (e.g. Briefing Books), and experience in regulatory submissions and interactions
- Flexibility to adapt to changing priorities and deadlines
- Ability to work independently and collaboratively, as required, in a matrix environment
- Team player, collaborative attitude, able to make a positive impact in the team

If you are attracted by this exciting opportunity and the prospects of joining a motivated international team operating on a global level, please send your CV and motivation letter mentioning the position "**Clinical Pharmacology Lead"** as the subject by email to: career@santhera.com.

Strictly no agencies

Recruitment agencies are kindly invited to refrain from sending to Santhera unsolicited CVs.