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, currently investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat (POL6014) to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed ex-North American rights to its first approved product, Raxone® (idebenone), 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

Head Clinical Science

at our Headquarters in Pratteln, Switzerland (close to Basel) on a full-time basis (100%).

Scope of work

To provide medical leadership and clinical development expertise (including, clinical trials design, trials protocol development and program life cycle strategy and planning across all phases of development, support data interpretation and input into medical regulatory strategy, business development and alliance management opportunities) on Santhera development programs, in interactions with clinical experts and regulatory authorities to support clinical development activities. This role will further help to build medical and clinical science expertise and resource across current and future program, portfolios and pipeline opportunities in line with Santhera growth plans. It represents the medical and clinical science function at the Santhera Clinical Program Committee.

The role reports to the Head Development working in close collaboration with internal Santhera development, business development, commercial, medical affairs and investor relations functions and externally with Health Authorities, Ethics committees, external consultants, key opinion leaders (KOLs), funding committees, investigators and patient advocacy groups.

The core responsibilities are:

- Provide medical and clinical science leadership and expertise in the definition and execution of clinical development plans and studies, managing budgets and resource allocation as the department function grows
- Participate in key Regulatory meetings as required and provide clinical and medical expertise and support in the development and finalization of relevant documentation
- Review of clinical data, providing medical expert analysis and interpretation and contribute to study reports, publications and relevant Regulatory and Market Access materials
- Perform medical monitoring and interpretation of safety data in collaboration with Pharmacovigilance
- Represent medical and clinical science function at the Santhera Drug Safety Board
- Organize and lead Data and Safety Monitoring Boards (DSMB) and act as liaison between Santhera and the DSMB

- Support development of study protocols, investigator brochures and review of other study related materials
- Develop & provide input to presentation materials for advisory boards, investigators meetings, scientific congresses, DSMB, and company presentations
- Interact with investigators & KOLs on clinical development & post-marketing programs as needed
- Support and collaborate with medical affairs, including medical education and the establishment and maintenance of contacts with investigators, KOLs and patient organizations
- Training of internal & external personnel on medical aspects of ongoing programs
- Participate in medical/scientific due diligence for in-licensing or out-licensing of ongoing programs
- Represent the medical and clinical science function at the Santhera Clinical Program Committee

Required background and experience:

- Medical Doctor (MD)
- At least 10 years relevant experience in successful drug development in Orphan drug / rare disease. Previous experience in working for small to medium sized organization in Biotech industry is a plus
- At least 10 years of experience with clinical development including clinical development strategy and clinical development plans
- Advanced medical writing skills
- Numerate with proven statistical skills to interpret, discuss and present clinical data
- Fluency in English (German or any other language is a plus)

Required competencies

- Good understanding of ICH guidelines and European and US regulatory guidance on drug development
- Ability to work in an agile and flexible manner within a small company and setting priorities with limited resources
- Ability to work with tight deadlines as well as strong planning, organizing and time management skills
- Strong verbal and written communication skills
- Ability to work independently to manage multiple projects in a fast-paced environment
- Strong problem solving and analytical skills
- Ability to identify opportunities / major issues and to communicate impact
- Reliable team-player

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 "**Head Clinical Science"** 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.