EG 427

PINPOINT GENE THERAPY

Job description

EG 427, a French clinical stage biotechnology company based in Paris that pioneers a new approach in gene therapy is looking for its:

VP Clinical Development

Full time position
Location: US East coast

Overview

EG427 is a clinical stage gene therapy biotechnology company leveraging non-replicating HSV-1 based viral vectors to develop a novel class of innovative therapeutics. Our initial focus on peripheral nervous system (PNS) disorders is based on the unmet need coupled with the high potential of HSV-1 vectors in order to provide major clinical benefit in these areas. With our headquarter and R&D Laboratory in Paris, our global footprint gives us the prospect to partner with leading organizations around the world, allowing us to deepen our understanding of disease mechanisms and progression.

Our team was built with deep expertise in gene therapy development, allowing us to efficiently advance our programs from pre-clinical to clinical development. Our experience in viral vector design, optimization and gene therapy manufacturing of herpesvirus viral vectors give us an alternative approach to develop gene therapies. Additionally, we are developing proprietary technology to potentially enable innovative gene therapy treatments in a variety of indications.

Our lead development compound entered clinical development with an ongoing first phase 1b/2a study in neurogenic detrusor overactivity in spinal cord injury patients This study has already generated very positive signal of efficacy and safety. As our pipeline matures, and with the expansion of the EG110A development program in neuro-urology, we are building up our clinical development capabilities. Novel vectors for other neurological indications are expected to enter clinical development in the coming years.

The VP Clinical Development will be responsible for the development of the clinical strategy for all development programs in coordination with the CMO/ Chief Medical Officer; design the respective clinical studies; and work with the Head of Clinical Operations on the clinical studies. The VP Clinical Development is expected to build the Clinical Development team for EG 427. The candidate is expected to work with the Regulatory consultants on the clinical aspects of Regulatory agency packages and meetings. The VP of Clinical Development is expected to seek external expert input into the clinical study designs and work with the consultant statistician on the statistical aspects of the clinical studies. Expertise in Clinical Development on a global level for phases 1b-3 in several indications is required as well as experience in representing Clinical development at expert advisory board meetings and Regulatory agency meetings. Profound knowledge of ICH GCP is essential.

The VP Clinical Development will have two direct reports in the initial phase: the Head of Clinical Operations and the Clinical Scientist (new position – to he hired)

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Key responsibilities

The VP, Clinical development:

- Will be part of the senior leadership team
- Develop the Clinical strategy in coordination with the CMO
- Be the author of the Clinical Development plan (CDP) for all compounds in coordination with the CMO and in collaboration with all functions involved
- Develop the timelines and budget estimates for the CDP in collaboration with the Head of Clinical Operations, Finance, CMC and all departments
- Be responsible to develop the respective clinical study protocols in collaboration with the consultant biostatistician, assigned Medical Writer, and all functions involved.
- Will seek external medical expert input into the study protocols, including organization of Clinical Advisory Board meetings with all functions involved
- Work collaboratively with the Head of Clinical Operations on the selection of the clinical CROs (contract research organizations) and study sites
- Work with the Head of Clinical Operations on medical aspects for the ongoing clinical studies
- Build up the Clinical Development team across all indications
- Will be the primary contact for all Medical Monitors at the respective CROs and work on specific safety aspects with the Medical Monitors and other functions as required
- Provide Clinical Development input into Regulatory Agency packages and represent Clinical Development at Regulatory Agency meetings
- Be able to present clinical study results internally and externally
- Be the manager for the Head of Clinical Operations and the Clinical Scientist (new position, to be hired) initially

Requirements

- MD degree is essential
- Board certification in Neurology
- Clinical development experience on a global level of at least 6 years in neurological indications
- Experience in developing the Clinical strategy for compounds in development and clinical study protocols
- Experience in representing Clinical development at Regulatory agency meetings
- Experience is presenting scientific-medical data to internal and external audiences
- Strong organizational skills and attention to detail

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- Collaborative approach to overcoming challenges
- Experience in managing direct reports
- Self-motivated, self-disciplined and able to function collaboratively as part of a team
- Strategic agility, strong critical and logical thinking with ability to analyze problems
- Strong ability to prioritize in a fast-moving environment
- Must be fluent in English (both spoken and written)
- Extensive knowledge of ICH GCP

We're looking forward to receiving your application (as a single PDF file) including:

- Cover letter
- Resume
- Contact details of referees
- Miscellaneous documents (if any) to support your application

Please send your application directly on our "Welcome to the Jungle" recruitment page.

EG427 is an equal opportunity employer and values diversity within our company. We do not discriminate in any way. We make hiring decisions based solely on your experience and skills.