Job Description
Vice President/Senior Vice President Clinical Development
August 2018

At Sesen Bio, we are committed to renewing life for people with cancer. We are a late-stage clinical company advancing fusion protein therapies based on our Targeted Protein Therapeutics platform. Our lead program, Vicinium™, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells.

The Opportunity

Sesen Bio is seeking a strategic minded physician leader for the role of Vice President/Senior Vice President of Clinical Development. The role will report to the acting Chief Medical Officer and work hand-in-hand with both the acting CMO and the CEO. This is an exciting time of growth of the organization.

Overview

The VP/SVP, Clinical Development, will provide leadership for the clinical team and the drug development programs in an outsourced model. The successful candidate will provide medical and scientific expertise on the strategy, design, execution and interpretation of data from clinical stage programs.

He/she is responsible for ensuring that all studies are conducted with the highest level of ethical and safety standards and are in compliance with GCP and all regulatory policies. Duties include primary interactions with investigators and monitors, functioning as the medical representative on the project team, and providing medical oversight.

The individual will partner with the acting CMO on late development activities for Vicinium™. He/she will work on the design, execution, data analysis and interpretation and reporting of clinical trials. The individual will interact closely with company management *(and participate on the senior team?).* A genuine interest and understanding of the science, desire to work in a highly collaborative organization, and deep passion about making a difference in the lives of patients are essential.

What makes this role special:

- Potentially gain an opportunity to play a key role in a late stage regulatory filing
- Potentially be part of a launch of a medicine for the treatment of patients with non-muscle invasive bladder cancer
- Responsible for developing strategy, as well as managing execution
- Collaborate with a small, collegial team
- Learn from leadership and a board of directors with deep experience
- Be part of an exciting company with the potential to meaningfully impact patients

Responsibilities

- Directly responsible for the clinical development strategy, including the clinical development plans and operational plans.
- Design and manage writing of clinical study protocols to support regulatory approvals.
- Present findings internally and externally (such as investigator meetings, regulatory agency meetings) acting as a spokesperson for Sesen Bio relating to the trial/indication.
- In collaboration with medical writing, the VP of Regulatory Affairs, and the acting CMO, review and interpret and prepare medical sections of regulatory documents.
- Review and interpret data for safety reports, IBs, NDA submission and responses to questions from regulatory agencies.
- Collaborate with CSO, clinical operations, regulatory, drug safety, statistics and data management in the development of development strategies and clinical studies; review and provide input on other protocol-related material
- Lead study team meetings and provide medical guidance in the execution of clinical trials.
- Secure, analyze and report on competitive intelligence related to successful conduct/execution of studies sponsored by other organizations and new data that may impact Sesen Bio studies.
- Responsible for internally and externally resourcing clinical development programs within functional area.
- Ensures the highest level of ethical standards are following, in compliance with internal SOPs, regulatory agencies, and laws.

Qualifications

- An MD degree with Board Certification or Board Eligibility in oncology
- 8+ years of drug development industry experience in oncology programs, including a thorough understanding of drug development from IND to NDA.
- Candidates must possess effective written and oral communication and influencing skills.
- Critical traits for success include strategic and proactive thinking, strong scientific and analytical skills, decisiveness and the ability to perform as a respected team member and leader.
- Strong attention to detail and focus on operational excellence
- Ability to work independently to achieve objectives and work on more than one project simultaneously.

This role is primarily based in Philadelphia, PA. For the right candidate, there are opportunities to work remotely and come into the office on a regular basis.

To apply, please send your resume to careers@sesenbio.com.

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