Early Development Program Leader

Job Overview

Domain Therapeutics, a biopharmaceutical company dedicated to the discovery and development of new drug candidates targeting GPCRs, is seeking a highly talented, experienced and self-motivated Early Development Program Leader to join an innovative, scientifically driven and fast paced team committed to developing breakthrough therapies in CNS, immuno-oncology and rare diseases.

This individual will be accountable for driving one of the company's lead programs from development candidate stage to phase I/II proof of concept. This position requires both strategic thinking and operational excellence. It is a high impact and highly visible role.

Key Responsibilities

- Responsible for the success of a program from development candidate stage to phase II proof-of-concept
- Understand disease area (biology, trends, competition) and the drug development process and challenges to create a vision for the asset, then design a development strategy and set the goals/direction for the program
- Lead the multi-discipline activities (translational research, CMC, non-clinical safety, regulatory, clinical trials) to drive program deliverables and meet program milestones
- Liaise with discovery research to facilitate translational research from preclinical into clinical development
- Identify, select and oversee CDMOs and CROs that will conduct IND-enabling studies, first-in-human and proof-of-concept trials
- Establish a network of consultants/experts in early drug development related activities to advise and to solve specific issues
- Plan and manage the program timelines and budget while ensuring the quality of the data generated
- Identify and anticipate challenges, develop risk management and mitigation planning
- Drive effective resolution of program issues and communicate with executive leadership regarding proposed solutions
- Represent the program at external stakeholder meetings/conferences
- Organize advisory boards with key opinion leaders when needed
- Support business development discussions and contribute to fund raising activities

Qualifications

- Advanced degree in a scientific discipline (PhD, PharmD or equivalent)
- Minimum of 5 years of biotech/pharma industry experience in drug process in the early development space (from drug candidate to phase 2) in immune-oncology

- Record of accomplishment in the field of small molecule and/or monoclonal antibody development
- Ability to create a clear purpose, global vision and a strategy for an early clinical phase asset
- Working knowledge of all functional areas of early development activities that include translational research, safety assessment, CMC, regulatory, clinical operations, clinical pharmacology and program management
- Strong capacity at managing and mobilizing multiple external partners/service providers involved in the program
- Understanding of scientific concepts and experience in translational research and biomarker development
- Familiarity with regulatory pathways and interactions such as scientific advice meetings at EMA or FDA
- Clinical experience in managing Phase 1/2 studies in immune-oncology is desirable
- Ability to work independently and to adapt to rapidly evolving situations and needs
- Strong commitment to delivering high-quality work
- Excellent oral and written communication skills
- Willingness to join an innovative, scientifically driven and fast paced biotech.
- Additional personal attributes: organized, pragmatic, flexible, persistent, open-minded, solution-driven