TOLREMO therapeutics

VP Clinical Development Oncology (80%-100%)

hybrid work possible

About us:

TOLREMO therapeutics' mission is to prevent non-genetic cancer drug resistance by dismantling the earliest defense to targeted therapies. Led by phenotypic insights, we discovered a pivotal mechanism that governs critical transcriptional resistance pathways. Our clinical compound TT125-802, a CBP/p300 bromodomain inhibitor, is an orally available small molecule designed to block these survival techniques to significantly improve the durability of established treatments. TT125-802 it is currently being evaluated in a Phase 1 dose-finding study as single agent. By stopping cancer drug resistance as it emerges, we aim to surmount a universal challenge for current and future targeted therapies for lasting patient benefit.

Position summary:

We are seeking a Vice President of Clinical Development Oncology to lead the clinical development of TT125-802. The successful candidate will be both hands-on and strategic, with responsibilities extending from medical monitoring to strategic planning. In addition, she/he will have a track record of designing and executing robust clinical studies in oncology, leadership in providing expert input in scientific discussions and proactive engagement in interactions with health authorities, regulatory bodies, and thought leaders. As a member of the executive management team, the person will be involved with asset and indication strategy and help assure that activities are executed within expected scope, budget, and timelines. This position will collaborate with a variety of internal and external partners and stakeholders, such as clinical investigators, scientists, key opinion leaders, Board of Directors, and potential investors.

Your responsibilities include:

- Oversee and manage all aspects of clinical development, including study design, protocol development, data analysis and interpretation.
- Develop and implement comprehensive clinical development strategies for both mono therapy trials and combination trials, with a focus on innovation and efficiency
- Be responsible for study design, protocol development, execution, and data analysis/interpretation, in conjunction with other relevant functions
- Serve as a hands-on medical monitor, closely tracking and reporting on patient safety, treatment efficacy, and drug tolerability.
- Manage and lead clinical operations team to execute and achieve functional responsibilities and program goals in compliance with GCP, ICH, and other global regulatory requirements
- Generate/review clinical components of key documents in support of regulatory submissions, including clinical section of IND's and CTA's, IND safety reports and annual reports, responses to regulatory authorities and Ethics Committees/IRBs, and other documents as appropriate
- Lead efforts to identify, build relationships and communicate with key investigators and trial sites to ensure successful execution of studies in compliance with global regulatory requirements
- Drive the overall clinical strategy of the ongoing clinical development programs and give in-depth clinical development advice on potential new projects (internal and external)

- Assume primary responsibility for the preparation of meeting abstracts, posters, and presentations related to clinical trial data.
- Analyze and interpret data expertly, and clearly communicate results both internally to Management and Board of Directors and externally to investors and pharma partners

Requirements:

- MD degree; Oncology board certification preferred but not required (if industry experience in Oncology drug development)
- 10+ years of clinical development experience in a biotech or pharmaceutical company covering early-stage clinical trials in oncology. Small company experience highly preferred
- Knowledge and understanding of early and late phase oncology clinical trial design and global regulatory requirements for study execution
- Experience with GCP/ICH/FDA and European regulatory requirements, clinical trial design and strategies, interpretation of clinical data and generation of supporting regulatory submissions of clinical study documents
- Experience cross-functional teams (e.g. translational medicine, pharmacovigilance, biostatistics, clinical operations, regulatory affairs).
- Ability to prioritize, respond to directives, and work in a fast-paced and changing environment
- Roll-up-your-sleeves-and-get-it-done attitude and committed to putting patients first
- Ability to develop and maintain relationships with significant key opinion leaders
- Demonstrated ability to represent the Company in a variety of internal and external settings, including board of directors, pharma and investors
- Exceptional written, verbal, and communication communication skills
- Ability to travel as needed to represent the company at various meetings and conferences.
- Trustworthy with highest integrity; committed to ethics and scientific standards

At TOLREMO you will encounter the motivating, dynamic and inspiring working environment of a biotech company addressing a key issue of cancer: resistance development to cancer therapies. If you feel you are up to the challenge and can contribute meaningfully to TOLREMO, we invite you to **send your CV and motivation letter** to hr@tolremo.com.