

## Director Biomarker Development (m/f/d)

### About Tubulis

The development of novel, effective and safe therapies for the treatment of cancer is one of the main challenges for modern medicine. We want to drive this process forward. The main goal of Tubulis is to become a leading company in the field of targeted therapeutics and antibody-drug conjugates (ADCs). With a strong team, our own technologies and innovative therapeutic concepts, we are ushering in a new era in the ongoing fight against cancer and share the vision of helping patients world-wide. Be part of a multidisciplinary and focused team, that works towards getting novel promising ADCs to patients with solid and hematological cancers.

### Be part of our team

The Director of Biomarker Development will lead the identification and implementation of appropriate biomarker strategies for Tubulis' innovative ADC programs. Together with colleagues from research, non-clinical and clinical development as well as with external experts, the incumbent will develop and execute biomarker candidate identification, assay development, validation and testing. Applicants should be able to serve an important role integrating biomarker efforts across our research, clinical and data science teams to support our drug discovery and development efforts.

### Responsibilities

- Provide scientific leadership in areas of biomarker discovery and development for ADC candidates
- Oversee development of translational and exploratory biomarker strategies to assess proof of mechanism, establish early signs of efficacy, enable proof of concept studies, patient selection and generate an understanding of the variability in patient response
- Support scientific input and review of all translational medicine aspects of clinical and regulatory documents, including but not limited to development plans, study protocols, clinical study reports, regulatory submissions and responses to any regulatory questions, etc
- Work independently and also in a cross-team environment with minimal guidance in defining, revising and progressing translational/biomarker plans for ADCs
- Utilize human and animal model data to support mechanism of action/validation studies for both non-clinical and clinical-stage ADCs drug candidates
- Ensure full compliance with the current global and local regulatory guidelines and GxPs
- Propose and develop innovative methods and technologies as well as new directions for project development
- Function as a scientific and business thought leader inside and outside of the company and a key link to external scientific & medical community

### Requirements

- PhD (and/or MD) with experience in either Cellular or Molecular Biology, Cancer Biology and/or Pharmacology with at least 5 years of pharmaceutical or biotechnology industry experience in biomarker discovery and development
- Thorough understanding of clinical trials and clinical strategy, experience with oncology drug development as well as analytical and clinical validation of biomarker assays
- Experience with identification and validation of pharmacodynamic and patient selection biomarkers and clinical implementation
- Expertise in establishing and running preclinical studies
- Experienced in authoring and providing regulatory guidance to team members on technical reports/summaries, suitable for inclusion in registration dossiers
- In depth understanding of the drug development process and of non-clinical development. Experience with ADCs is a plus
- Familiar with ICH, FDA and other regulatory guidance and regulations relevant to biomarker development
- Excellent communication skills and proven ability to collaborate with interdisciplinary teams and CROs. German is a plus
- Excellent managerial and leadership skills. Must be highly organized and extremely analytical with strong problem-solving skills
- Able to work independently and work well in a team and in a fast-paced environment

### We offer

Flat hierarchies and short decision-making processes; open corporate culture; possibility of mobile working; unlimited contract after probationary period; 30 days' vacation; strong team spirit; personal appreciation of values; multicultural and global team and high level of collegiality; regular team events; mobility allowance; GUV; pleasant office atmosphere; modern technology standard.

We look forward to receiving your application with details of when you can start and your salary expectations.

By email to [career@tubulis.com](mailto:career@tubulis.com) - more information at [www.tubulis.com](http://www.tubulis.com)