VICE PRESIDENT OF ONCOLOGY
CLINICAL DEVELOPMENT

Job Title:	Vice President, Oncology Clinical Development
Reports to:	Chief Medical Officer
Classification:	Full-time, Exempt, Salaried

Company Summary: Aeglea BioTherapeutics, Inc. is an Austin, TX based biotechnology company committed to developing engineered human enzymes for the treatment of genetic rare diseases and cancers associated with abnormal amino acid metabolism. The company's engineered human enzymes are designed to degrade specific amino acids in the blood in order to reduce toxic levels of amino acids in in genetic rare diseases or to starve tumors dependent on amino acids by reducing blood levels below the normal range. Aeglea's clinical program for its lead product candidate, AEB1102, includes three recently initiated Phase 1 clinical trials, studying AEB1102 for the treatment of patients with Arginase I deficiency as well as patients with solid tumors or hematological malignancies. The company is building a pipeline of additional product candidates targeting key amino acids, including AEB4104, which degrades homocystine, a target for metabolism genetic rare disease, as well as two potential treatments for cancer, AEB3103, which degrades cysteine/cystine, and AEB2109, which degrades methionine.

Position Summary: Aeglea BioTherapeutics based in Austin Texas, is actively recruiting for a Vice President of Oncology. This will be a critical member of the Clinical Development team and key contributor to the Company's drug development programs in Oncology. The Vice President of Oncology, will perform various duties in support of clinical development including: medical input for specific disease areas and medical review of key trial data-related documents, and representation of the company in investigator meetings and key relationships in the field. This is a hands-on position. This position reports to the Chief Medical Officer.

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Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following:

- Provide the overall strategic clinical direction and medical leadership for Oncology development-stage programs, serving as the medical expert on all clinical and medical matters.
- Responsible for all areas of clinical affairs including clinical trial strategy and design, the preparation of clinical plan, oversight of studies at clinical CROs and clinical investigators, medical monitoring activities, and medical affairs (medical information and patient services, regulatory review, medical liaison, drug safety functions). Collaborate closely with the VP of Biometrics for DMC, data management, and statistical data analysis activities.

- Stay current with GCP and regulatory requirements in the preparation and review of the clinical module for FDA and international regulatory approval of Phase I-III studies.
- Manage relationships with key opinion leaders and communicate clinical strategy to investors.
- Obtain key stakeholder review and endorsement of clinical and medical matters.
- Interface with preclinical research and development leadership in the evaluation and analysis of product opportunities.
- Develop clear clinical trial strategies, design and write study protocols, monitor, document, and interpret clinical study data.
- Participate in the evaluation and selection of clinical vendors and consultants, including direct interface with trial sites and clinical investigators.
- Implement safety strategy across studies, including regular review of safety data and response to safety issues.
- Responsible for preparation of clinical sections of regulatory documents (INDs); prepare for meetings with FDA/EMA.
- Interface with Business Development and Finance to provide subject matter expertise on all clinical strategic initiatives, including competitive and complementary products, technologies and companies.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

Education/Experience: The ideal candidate will offer:

- M.D. Board eligible/certified in a clinical subspecialty with an active unrestricted license in US (or EU countries)
- Direct experience in clinical medicine treating patients.
- 10-15 years of pharmaceutical / biotech experience in a leadership role in early stage drug development in hematology and oncology including direct experience managing, planning, organizing, implementing, and completing phase I-III clinical trials.

Knowledge, Skills and Abilities:

- Strong working knowledge of the FDA and other regulatory organizations (EU), especially with regard to the approval of novel biologics (including drug conjugates) for human testing at CBER/CDER/EMEA and responsibility of OBP and ONDQA for these molecules.
- Strong working knowledge of GCPs, principles of ICH GCP, roles of the IRB/IEC sponsor/investigator, preparation of the clinical trial protocol, IB and clinical modules for FDA regulatory phase I-III approvals.
- Ability and desire to work collaboratively with senior scientific and business leaders to execute on near and long term plans, and to adapt to rapidly changing business conditions.
- Demonstrated track-record of success in: leading cross-disciplinary, clinical development project teams; integrating and evaluating the work of multiple functions; managing both internal and contract resources.
- Track record of progressing clinical candidate therapeutics through registered studies.
- Leading-edge knowledge of early clinical stage drug development efforts, including typical hurdles and challenges, and experience in mitigation strategies.

- Experience in preparing and reviewing documents for clinical development, including the coordination, review and sign-off processes to ensure high-quality document submissions to IRBs, health authorities and regulators.
- Molecular understanding of biologics and the ability to strategically incorporate this knowledge into drug development and regulatory plans.
- A solid understanding of how to leverage biomarkers and translational research to guide clinical development and the development of companion diagnostics.
- Knowledge of assays and metrics for safety, clinical PK, and clinical outcomes.
- Willingness to recruit, mentor and manage clinical and regulatory staff, both internal and external.
- Self-motivated, approachable, articulate team player who values collaboration and transparency and who possesses the highest level of integrity.
- Strong written and oral communication and presentation skills.

Work Environment:
This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally is required.

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.