Position:

Director, Clinical Pharmacology

About the Company:

Dren Bio (the "Company") is a privately held, clinical stage biopharmaceutical company focused on developing therapeutic antibodies for the treatment of cancer, autoimmune and other serious diseases. The Company's management team and scientific advisors have profound expertise covering the discovery and development of engineered antibodies designed to selectively target and deplete pathological cells. Dren Bio's pipeline is currently comprised of two distinct drug discovery programs. The Company's first program surrounds DR-01, its lead product candidate, which induces antibody-mediated killing of a cell type that is responsible for a multitude of hematologic malignancies and plays a key role in various autoimmune diseases. The Company's second program surrounds its Targeted Myeloid Engager and Phagocytosis Platform, a proprietary bispecific antibody-based technology that provides a novel mechanism of action to selectively engage myeloid cells for (1) targeted depletion of pathologic cells and other disease-inducing agents and (2) inducing localized immunostimulation. The engagement of antigen presenting cells has the potential to elicit a sustained, durable response.

Function: Clinical Pharmacology

Level: Director

Location: Foster City, CA

About the Opportunity:

Dren Bio is seeking a Director of Clinical Pharmacology who will be responsible for development and implementation of clinical pharmacology and pharmacometric strategies for the company’s growing portfolio of therapeutic antibodies with enhanced ADCC and/or targeted myeloid-engaging function. The Director will work in close partnership with other key functions such as Clinical Development, Biostatistics, Regulatory Affairs and Translational Science to plan and review study designs, analyze and interpret pharmacokinetic and pharmacodynamic data; apply Model-Informed Drug Development and principles of quantitative clinical pharmacology to ensure optimal drug development and author the clinical pharmacology sections of regulatory documents.

Role and Responsibilities:

- As part of a cross functional team, develop and execute clinical pharmacology and pharmacometrics strategies for biotherapeutic drug candidates at all phases of clinical development.
- Develop clinical pharmacology plans to support developmental therapies (many are first in class) in the Dren Bio pipeline and represent the clinical pharmacology function in health authority interactions.
- Author and review relevant sections of IND/CTA filings as well as NDA/MAA/BLA submissions and other key documents including investigators brochures, clinical study protocols and reports, and regulatory briefing documents.
- Analyze, interpret, summarize, and present clinical pharmacology data to internal project teams, senior management, and to global health authorities.
- Work closely with preclinical teams to ensure adequate study design to support FIH studies. Analyze and interpret preclinical data to support dose and regimen selection for FIH studies.
- Provide modeling and simulation and characterize exposure-response relationships to optimize dose selection for studies and for special populations.

Education, Experience and Qualification Requirements:

- PhD in pharmaceutical sciences, pharmacology or equivalent professional degree e.g. PharmD.
- 7+ years of experience in clinical pharmacology, modeling & simulation in the biopharmaceutical Industry.
- Experience in leading the design and implementation of clinical pharmacology studies including special populations, ethnic sensitivity, and pediatric studies and integrating results into regulatory submissions, and product labels.
- Established track-record of interaction with global health authorities, authoring regulatory documents and successful INDs (required) and NDA/BLAs (preferred).

Core Competencies, Knowledge and Skill Requirements:

- Team Player, with profound understanding that clinical development is a cross-functional effort.
- Active and effective communicator, both written and oral
- Hands-on experience with NCA using Phoenix WinNonlin and quantitative PK/PD approaches.
- Expertise with population modelling and simulation software (NONMEM, Monolix, R, etc)
- Prior experience in large molecule and oncology drug development
- Knowledge of relevant global regulatory requirements and guidance

Salaries, Benefits and Other Employee Perks:

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. The base pay range for this position at commencement of employment is expected to be between $190,000 and $240,000 per year. At Dren Bio, pay ranges are determined by role, level(s), and location. The range displayed in this job posting reflects the minimum and maximum new hire pay for candidates located across all United States job markets. Within the range, individual pay will be determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, Dren Bio's Human Resources department can share more about the specific pay range based on the market location of the candidate.

Employment Practices:

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.

Interested Applicants:

Please send resume and cover letter to careers@drenbio.com