Job Description

Job Title

Clinical Science Lead / Program Lead
(Future Candidate for Head of Clinical Development)

Attractive Aspects of the Role

With substantial funding support from the Japanese government (AMED), you will have the opportunity to be directly involved in the clinical development of our novel hematopoietic stem cell therapy product, CLD-001, in the United States.

Our current clinical development structure is highly global, consisting of:
- a Japanese COO (Board Director)
- a U.S.-based clinical physician consultant
- a U.S.-based regulatory consultant
- a U.S.-based medical advisor

This structure provides you, from the very beginning, with an exciting opportunity to take a leadership role in global development.

Job Description

Depending on your experience, you will be engaged in the following clinical science and operations activities:

Responsibilities

- Protocol Detailing and Updates (Clinical Science):
  - Pre-IND meeting with the U.S. FDA completed; broad agreement reached on target indication and protocol framework.
  - Collaborate with our medical advisor and KOLs to refine and elaborate protocol details, especially inclusion/exclusion criteria.
- Site Selection (Clinical Operations):
  - Representative candidate sites already identified.
  - Strengthen relationships with additional sites and KOLs to prepare for trial initiation.

- Clinical CRO Selection (Clinical Operations):
  - Evaluate and select from several candidate CROs.
  - Manage CRO activities post-selection.
- Preparation of IND Submission Documents (Clinical Science / Operations):
  - Lead preparation of Investigator's Brochure (IB), protocol, informed consent forms, and related documents, with external consultants as needed.
- Grant Management for the AMED "Pharmaceutical Startup Ecosystem Strengthening Program" (Clinical Science / Operations):
  - Collaborate with the COO to oversee clinical development progress and prepare reports and documentation for AMED.
- Other Responsibilities:
  - Participate in meetings related to U.S. clinical trials, troubleshoot issues, and communicate directly in English with U.S.-based stakeholders.

Company Information

Company Name: Celaid Therapeutics Inc.

Website: https://celaidtx.com/en/

Department: Clinical Development Department (to be newly established)

Reporting to: Chief Operating Officer (COO, Board Director)

Company Overview

Representative: Nobuyuki Arakawa, President & CEO

Headquarters: UTokyo Entrepreneur Lab., South Clinical Research Bldg., 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8485, Japan

Established: 2020

Origin: Spin-out from the University of Tokyo and the University of Tsukuba

Business: Development of next-generation hematopoietic stem cell (HSC) therapies and HSC-based gene/cell therapy platforms

Company Highlights

Technological Superiority:

- Proprietary expansion technology enabling high-purity and large-scale expansion of CD34+ cells (400-

fold in 2 weeks).
- Demonstrated superior efficacy in vivo compared to competitors.
- International patent applications filed; patents granted in Japan and other regions.

Pipeline Development:
- Lead program CLD-001 targeting severe pediatric non-malignant diseases.
- Designed to address donor shortages, graft failure, and GvHD.
- Phase 1/2 trial planned in the U.S. after GMP manufacturing and GLP safety studies.

Platform Technology:
- Applying HSC expansion technology to gene therapy and iPSC-derived products.
- Partnerships established with global pharma and biotech companies.

Fundraising:
- Raised JPY 1.16 billion in Series A (as of Sep 2024).
- Secured government grants: up to JPY 200M (NEDO) and up to JPY 2.7B (AMED).
- Series B financing progressing smoothly.

Management & Team:
- Experienced professionals from leading pharma and CROs (non-clinical, CMC, clinical, finance).
- Development of CLD-001 and BD activities conducted in collaboration with U.S.-based consultants.

Background of Recruitment

With the successful completion of Series B financing and substantial grant support from AMED, we are now well-positioned to accelerate CMC and clinical trial preparations in the United States.

Open Positions

1 Clinical Science Lead

1 Program Lead

(Final job title determined by experience and skills)

Start Date

Negotiable

Requirements

Must-have:

- Experience in Clinical Science or Clinical Development at a pharmaceutical company or CRO
- Expertise in protocol design, trial execution, and regulatory submissions
- Strong communication skills in English and Japanese

Preferred:

- Experience in hematology, oncology, or regenerative medicine
- Leadership experience in global clinical trials
- Strategic thinking and cross-functional leadership capabilities

Employment Conditions

Type: Full-time, permanent employee (3-month probationary period; conditions may vary)

Compensation: Competitive, commensurate with experience and skills

Work Hours: 09:30 – 18:30 (60-minute break)

Benefits: Health Insurance, Welfare Pension, Employment Insurance, Workers' Accident Insurance

Holidays: Weekends, national holidays, New Year holidays, paid annual leave

Selection Process

2–3 interviews (online or in-person)