Director, Clinical Development

SUMMARY:

Icosavax, Inc. (NASDAQ: ICVX) is a publicly traded clinical stage biopharmaceutical company leveraging its innovative VLP platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases. Icosavax's VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which it believes will induce broad, robust, and durable protection against the specific viruses targeted. Icosavax's pipeline includes vaccine candidates targeting respiratory syncytial virus (RSV), human metapneumovirus (hMPV), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) with two Ph1/2 trials. Based in Seattle, Icosavax was formed in 2017 to advance the breakthrough VLP technology from the Institute for Protein Design at the University of Washington with the goal to discover, develop, and commercialize vaccines against infectious diseases.

Icosavax is seeking a highly capable MD with early phase clinical development experience to lead the clinical development of Icosavax's programs on cross-functional, matrix project teams and/or clinical sub teams. This individual will serve as a clinical program leader for one or more of Icosavax's development programs and as a subject matter expert, who works effectively with internal and external partners. The successful candidate will understand what it takes to excel in a dynamic small company environment. They will be part of a collaborative team that helps to drive and push one another to continued levels of success.

JOB DUTIES:

- Lead the successful creation of a cohesive clinical development strategy for assigned programs.
- Contribute to the integrated product development plan and clinical and regulatory strategies and their execution:
    - Author and provide clinical input and oversight for all clinical documents, including, but not limited to applicable study synopses, protocols, informed consent forms, vaccine clinical development plans, statistical analysis plans, and other protocol-related documents.
    - Participate in and contributes to regulatory meetings, including preparing briefing documents and annual reports.
    - Responsible for clinical sections of Investigational New Drug and other global regulatory filings, Investigator Brochures and DSURs.

- Support the development and execution of clinical trials, including the identification and management of clinical investigators and sites, consultants, and/or Clinical Research Organizations (CROs)
- Ability to work and partner with colleagues of cross-functional areas and members of the global program teams.
- Responsible for medical monitoring activities, assessing issues related to protocol conduct and/or individual subject safety. Assesses overall safety information for trials and vaccine candidates for Icosavax-sponsored studies.
- Oversees ClinOps scientists with respect to assessment of these issues and makes decisions regarding study conduct related to scientific integrity.
- Other responsibilities related to the design and execution of global clinical development programs include:
    - Responsible for and providing expert strategic and tactical input into clinical development plans.
    - Responsible for acting as liaison with research and/or development personnel both internally and with external collaborators/principal investigators to ensure all regulatory requirements for GCP studies are met and proper handling, tracking, and evaluation of samples from studies is secured.
    - Responsible for overseeing clinical trial registration and reporting, including collection and interpretation of safety and immunogenicity data while paying detailed attention to the quality, accuracy, and timeliness of clinical study reports from Icosavax's clinical trials to provide final review and signoff of such clinical study reports.
- Oversee and manage the development and execution of clinical strategy:
    - Responsible for the creation and oversight of operational timelines and budgets for clinical development activities, along with Clinical Operations and Project Management personnel.
    - Ensure compliance with Code of Federal Regulations, Good Clinical Practices, ICH Guidelines, and all applicable regulations. Develops clinical standard operating procedures and processes as needed.
    - Responsible for risk-map and development of risk mitigation strategies to ensure operational excellence.
    - Work with external experts to present and publish clinical trial data. Interfaces with key opinion leaders and manages scientific presentations at advisory boards, key scientific meetings, and external committee meetings.
    - Work comfortably in matrix environment with other functions and provide clinical expertise to portfolio and project management. Other duties as needed.

EDUCATION, EXPERIENCE, KNOWLEDGE, AND SKILLS:

- MD required, Board certification or eligible in geriatrics, infectious diseases or immunology a plus.
- 12+ years of experience in Clinical Development and/or clinical trial experience in the pharmaceutical industry or clinical research organization required.
- Biologics development experience required, with expertise in the development of products for respiratory infections an advantage. Strong preference for vaccine experience.
- Proven track record in bringing products through early phases of development including successful progression of product candidates from preclinical through phase I. Advanced development (phase II/III) experience a strong plus.
- Expertise in CFR, GCP, and ICH Guidelines.
- IND/MAA submission experience.
- Ability to proactively anticipate issues, solve problems, and multitask.
- Ability to thrive in multiciliary, matrix teams and to foster open and trusting partnerships.
- Knowledge of regional/global requirements.
- Excellent self-management, organizational, and verbal/written communication skills.
- Able to present fluently to internal and external audiences.
- Demonstrated experience in a startup environment and interest in rolling up sleeves to perform in a hands-on capacity.

PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment (i.e., computers, phones, etc.).
- Travel up to 25%

OTHER:

- Location: Seattle, WA is preferred, or remote in US
- Must be eligible to work in the USA
- To reduce the presence and severity of COVID-19 cases in the workplace and in our communities, Icosavax requires all newly hired employees to be fully vaccinated against COVID-19 before commencing employment, subject to reasonable accommodation and other requirements of applicable federal, state, and local law.