Medical Officer, Consultant

Sernova Corp – London, ON

Company Summary: Sernova is a publicly traded, clinical-stage regenerative medicine company developing therapeutic technologies using an implanted medical device, the Cell Pouch™, and immune protected therapeutic cells to improve the treatment and quality of life of people with chronic metabolic diseases such as insulin-dependent diabetes, blood disorders including hemophilia, hypothyroid diseases and other diseases treated through replacement of proteins or hormones missing or in short supply within the body. The Cell Pouch™ is a novel, scalable, macro-encapsulation device designed for the long-term survival and function of therapeutic cells. The device is designed to incorporate with tissue, forming highly vascularized chambers for the transplantation and function of therapeutic cells, allowing them to release proteins and hormones as required by the body's natural functions to treat diseases. The device, along with therapeutic cells, has been proven to provide a biologically compatible environment for insulin-producing cells in humans and is currently in Phase I/II Clinical Trial at the University of Chicago Medicine.

Position Summary: The Medical Officer consultant (MO) is a contract, part-time position. The MO will work with the Sr. Director R&D/Clinical Program Manager and report to the Chief Executive Officer. The primary role of the MO will be to provide support for Sernova's pipeline of clinical development programs on an as-needed basis. The MO will work with Sernova's clinical team and provide support to the strategy, direction, and execution of the company's clinical development plans. This is a unique opportunity to be a major contributor to the success of a well-positioned, growth stage biotechnology company.

Essential Duties and Responsibilities:

- Lead interactions with academic thought leaders, investigators, cooperative groups, and other clinical stakeholders
- Provide clinical support and work with other members of the management team to develop and communicate the overall clinical and corporate strategy
- Support clinical aspects of regulatory strategies and interactions with Health Authorities
- Represent the Company and its clinical programs to external audiences, including the investment, medical and regulatory communities, as well as pharmaceutical or biotechnology industry collaborators/partners
- Work with the Clinical Research team, including the Clinical Trial CRO Medical Monitor and Clinical Site with direct input into the Clinical Operations, Patient Advocacy, Medical Affairs
- Play a significant role in the analysis and interpretation of clinical trial data and the reporting of clinical trial results

Qualifications:

- MD with Board Certification in Endocrine diseases (such as Diabetes, Thyroid disease) and Hemophilia Disease knowledge preferred
- 10 years minimum experience in clinical practice treating patients and pharmaceutical and/or biotechnology industry experience as a sponsor working on investigational products an asset
- Multiple years experience leading a clinical group, including clinical/medical affairs and clinical operations, is preferred

- A proven success record in Phase I-II and advanced clinical research studies and trial design as well as the successful submission of IND's and marketing approval-directed filings (BLA's, NDA's, and MAA's), is preferred

Knowledge, Skills, and Abilities:

- Knowledge of relevant FDA regulations and guidelines as well as those of the EU and other health authorities
- Experience in interactions with FDA personnel is essential
- Experience in interactions with other health authorities an asset
- Experience with, or strong knowledge of Diabetes, Hemophilia, or Thyroid Disease development
- Experience or knowledge of orphan or genetic rare disease drug development a plus
- Experience in translational medicine, clinical pharmacology, and early-stage development is desirable
- Excellent knowledge of the competitive environment for drugs in the Hematology/Oncology marketplace and research and development pipelines
- Must have a thorough knowledge of clinical research concepts, practices, and GCP and ICH Guidelines
- The successful candidate will read, write and speak fluent English, possess excellent communication skills and will be capable of articulating the Company's clinical and regulatory strategies and progress to a wide audience including the CEO, the Board of Directors, Company employees, and the investor community
- Should have proven skills as an effective team player who can engender credibility and confidence within and outside the company
- Must be willing and able to be "hands-on"
- Effective leadership, people management, communication skills, and a team builder management style are essential
- Must have outstanding executive presence
- Must be science- and data-driven
- Must have the highest ethical standards

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 may be required; it is anticipated that this will be a small part of the work time as the clinical trial requires it.

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.

Compensation: Commensurate with experience.

To Apply: Please submit your resume to the attention of Sr. Director R&D at admin@sernova.com