Apellis

Title: Sr/Medical Director, Rare Disease

Location: Waltham, MA

Reports to: EVP of Clinical Development and Medical Affairs

The Medical Director for Rare Disease will be the primary point person for medical monitoring and oversight of rare disease clinical programs, including Complement Dependent Nephropathies. This individual will monitor clinical studies, review and interpret clinical trial data, author clinical study and regulatory communications and documents, as well as monitor all competitor activities and data. Additionally, this person will contribute to review of clinical trial data as well as collect external data and relevant competitive intelligence.

Specific Responsibilities:

- Providing specific rare disease and nephrology expertise and strategic insight to further identify additional development opportunities for APL-2
- Medical monitoring, coding, and data cleaning in collaboration with Clinical Operations
- Authoring clinical sections in regulatory documents not limited to IND submission and annual updates, study protocols, investigator brochures, briefing documents, and other study-relevant documents such as patient informed consent documents
- Writing manuscripts, publications, or other documents intended for external audiences
- Acting as an internal resource for functions requiring clinical input on select drug(s) including primary point of contact for clinical trial staff at study sites for clinical issues as well as regulatory, safety and other functions
- Preparing safety charters, DMC charters, or other specific management plans and manuals in a cross-functional team
- Supporting or preparing data interpretation and clinical trial reports
- Preparing Investigator Alert letters and SAE reports in collaboration with Clinical Operations as required
- Contributing in an active and ongoing manner to the scientific, clinical, and commercial development of current and future product candidates
- Contributing to Strategic or Clinical Advisory Boards and, Supporting Medical Affairs as needed

Requirements:

- MD degree with 8+ years of experience with at least 5 years of rare disease and/or nephrology and preferably some phase III clinical trial experience
- Experience initiating and managing or participating in clinical trials for industry
- Successful academic research publication history or history of medical practice in a relevant field

- Experience presenting medical data and concepts to a variety of audiences (medical, scientific, vendors) in a credible and engaging manner
- Solid understanding of the clinical landscape relevant to patients and health care practitioners in the field
- Strong technical/analytical skills to identify and solve problems
- Self-motivated, assertive, and self-confident with the ability to act with urgency and passion
- Proven ability to work with a high level of integrity, accuracy, and attention to detail
- Ability to make thoughtful, integrated, timely and meaningful decisions and take corresponding actions
- Willingness to work collaboratively by incorporating diverse perspectives and appropriately managing relationships
- Proactively seek out and recommend process improvements
- Entrepreneurial, enjoys working in a fast-paced, small-company environment.
- Demonstrated application of critical thinking skills
- Proven ability to multitask, prioritize and execute corporate objectives and goals
- Ability to operate autonomously in a fast-paced early phase company

Company Background:

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit http://apellis.com/about.html to learn more.

EEO Statement:

Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.