POSITION PROFILE:

Vice President Clinical Sciences

www.acertx.com

July 2021

Company Overview

We are a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Acer was founded in 2013, went public in 2017 and raised $100 million to date. Acer's pipeline includes four programs: ACER-001 (sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); EDSIVO™ (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; ACER-801 (osanetant) for the treatment of induced Vasomotor Symptoms (iVMS); and ACER-2820 (emetine), a host-directed therapy against a variety of infectious diseases, including COVID-19. Each of Acer's product candidates is believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation and/or accelerated paths for development through specific programs and procedures established by the FDA.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Acer's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

Acer has a strong company culture and is committed to creating and maintaining an environment that values individual rights, hard work, fosters creativity, and promotes success. The Company is growing and is fueled by the talent and expertise of our employees and driven by the commitment to treating patients with significant unmet medical needs.

Location – United States

As a part of the Acer team, you will have the opportunity to work where you're most productive. We have offices in Newton, Massachusetts and Bend, Oregon. Some travel, post COVID-19 pandemic, to our East Coast (Newton, MA) and West Coast (Bend, OR) offices may be required, as well as other US meeting locations.

However, most of us work out of a home office, co-working space, in a rainforest, at the beach, on a train, in a plane, you name it, we're there. We're a talented, unconventional and collaborative team that knows no boundaries who are always looking to work smarter and support one another. In addition to ultimate work flexibility, we also provide world-class benefits to support the ongoing health and wellness of our employees and their families.

Reporting Relationship

The Vice President Clinical Sciences will report directly to the Chief Executive Officer.

Job Description

The Vice President Clinical Sciences will ensure the design of scientifically robust clinical trials that will be conducted to support new and modified Company products. The incumbent brings extensive scientific and management skills to enhance program/portfolio progress and provide insight regarding strengths and liabilities in drug development programs. The person must be able to identify key issues which affect 'go/no go' decisions, are of strategic importance and have successful interactions with regulatory agencies. The role is a key member of the clinical leadership team, provides scientific expertise, and can forge excellent collaboration and relationships across the organization.

Responsibilities

- Lead strategy for development programs in all Therapeutic Areas (TAs), including significant contribution and authoring of the target product profile for Company products
- Design and analyze results of Clinical Pharmacology studies including integration of results into program decision-making and regulatory filings/interactions
- Responsible for ongoing data analysis, summarizing study results for preparation of nonclinical and clinical documents, publications and supporting project teams with scientific information as subject matter expert
- Lead Clinical Pharmacology for all drug development programs and assure appropriate study design to facilitate clinical advancement (e.g., design of dose finding studies) to improve the probability of success
- Contributes as a subject matter expert to the development of various clinical components for key documents (e.g., Clinical Trial Protocols, Investigator's Brochures, Informed Consent Forms, Clinical or Bioanalytical Manuals, Clinical Study Reports (CSRs), regulatory documents including maintenance of IND/CTA, product licenses, registration dossiers, value dossiers) with high quality and consistency with development plan and contributes substantially to the target product profile of Company programs
- Develops scientific aspects including analysis and rationale for clinical documents and sections of regulatory documents as needed, drug safety reports, and other key clinical documents. Draft text and figures for clinical presentations, abstracts, posters and manuscripts for publication. Author the Summary of Clinical Pharmacology and other module sections for NDAs or other ex-US marketing applications
- Responsible for data review, analysis, and scientific interpretation as well as preparation and presentation of results for informed decision-making
- Participate in leadership and management as Clinical Science representative to ensure deliverables are met according to timelines, budget, quality standards and operational procedures, within a global multidisciplinary cross-functional team
- Partner with cross functional teams to successfully execute clinical studies.
- Work closely with medical monitor on clinical activities and clinical site interactions
- May support technical due diligence in Business Development & Licensing (BD&L) activities
- Other responsibilities as assigned

Qualifications

- Ph.D. degree with at least15 years of industry experience in pharmacokinetics, pharmacology or pharmaceutical science
- Strong understanding of clinical pharmacology with industry experience in nonclinical and clinical stage drug development
- Proficiency with hands-on analysis and data reporting tools
- Experience with exposure response analysis, mechanistic PK/PD modeling, and population PK modeling. PBPK modeling experience
- Experience authoring Clinical Pharmacology sections of regulatory submissions
- Experience in drug development across diverse TA's and ability to rapidly master new scientific areas. (Experience in rare diseases a plus.)
- Requires a detail-oriented self-starter with excellent organizational, planning, and follow-up skills, as well as communication, teamwork, and interpersonal skills
- Demonstrated ability to adapt to changing priorities and work effectively in a fast-paced organization to achieve results, meet tight competing deadlines, juggle multiple priorities
- Demonstrated ability to facilitate appropriate team decisions
- Solid understanding of medical terminology, and FDA and ICH regulations/guidance specific to clinical research and general product development in the pharmaceutical industry
- Experience reviewing nonclinical, clinical and CMC documentation (e.g., nonclinical study reports, clinical protocols/study reports, Investigator Brochures, CMC information/data) and contribute to content as needed
- Understands issues, challenges and opportunities by comparing data from different sources to draw conclusions and then choose a course of action or develop the appropriate solution
- Capable of effectively negotiating with others while maintaining composure

Compensation

Acer seeks an individual of exceptional ability and will offer a competitive compensation package commensurate with candidate's individual skills and experience.

The Acer Ethos

We founded Acer on the fundamental mission that we will invest in developing innovative therapies and make them broadly accessible for people impacted by serious rare diseases with significant unmet medical need. In an era when the pharmaceutical industry is making huge strides in advancing therapeutic options for rare conditions, that may not sound atypical. But we believe we have a better way and it will deliver significant value to patients and their families and caregivers, healthcare systems and society.

Be led by patients, their families and caregivers and clinicians.

We don't just put patients first, we are fueled by their resilience to adversity. That's why patients, their families and caregivers lead us in how to think about shaping our drug development programs so that our products will deliver optimal outcomes and earn the commitment of treating clinicians.

We recognize that drugs can offer tremendous benefit to patients and clinicians alike, but often leave both with an incomplete promise. That's why we engage with patient and clinician communities in our targeted pipeline areas and listen to their needs in order to reflect their inputs early and throughout our drug program development.

Indeed, such collaboration enables us to solve challenges and design solutions together.

Our Core Principles

1. Obligation to prioritize the Patient & their Family
2. Be Compassionate
3. Respect other's perspectives
4. Responsibility to do what's right – always!
5. Total Transparency
6. Celebrate Diversity
7. Humility
8. Be Courageous
9. Accountability
10. Be Unconventional

We will be accountable to this Ethos and Core Principles. We encourage open and transparent communication that can help us to drive our mission forward. We may seem impatient, but it is only because we want to get there faster. We are in this, together.

Acer is committed to continuously work to create a diverse and inclusive workplace and is proud to be an equal opportunity employer. Our goal is to promote a culture where diversity of thought, backgrounds, gender, gender identity, race, national origin, sexual orientation, religion, genetics, disability, age or veteran status, is given equal consideration for employment.