Vice President, Clinical Development

Reports to: Chief Medical Officer

Classification: Exempt

Company:
CymaBay Therapeutics, Inc. (NASDAQ: CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. The Company's lead program is seladelpar, a potent, selective, orally active PPARδ agonist currently in development for the treatment of patients with the autoimmune liver diseases primary biliary cholangitis (PBC) and NonAlcoholic SteatoHepatitis (NASH). Seladelpar is uniquely suited as a treatment for liver disease. Preclinical and clinical data support its effect on bile acids synthesis, inflammation, fibrosis and cellular metabolism. PPARδ has been shown to regulate genes in hepatocytes, cholangiocytes, Kupffer cells and stellate cells. In addition to seladelpar, CymaBay's pipeline is complemented by a Phase 3 ready gout program that is partnered in the U.S. with Kowa Pharmaceuticals, as well as several earlier stage molecules.

The Company has previously announced positive data from its Phase 2 study of seladelpar in patients with PBC, and has advanced into a Phase 3 study. The unmet medical need and significant market size of NASH represents a tremendous opportunity for CymaBay, and the Company commenced a Phase 2b Proof of Concept Study in 2018 in that indication. CymaBay believes seladelpar could potentially benefit patients affected with Non-Alcoholic Fatty Liver Disease (NAFLD) who are further at risk of developing NASH.

Summary:
Represent the Company to the medical community, patient's community, clinical investigators, regulatory authorities, and business partners. Responsible for establishing the strategy and executing the clinical development activities for seladelpar, currently in phase 3 development for Primary Biliary Cholangitis, a rare auto-immune liver disease. For this indication, seladelpar has received orphan drug status in both the US and Europe. Seladelpar has also been granted both a Breakthrough designation by the FDA and the PRIME (PRIority Medicines) designation by the European Medicine Agency. As such seladelpar potentially represents a very important new therapeutic options for patients suffering from Primary Biliary Cholangitis..

This is a key position within CymaBay that will directly impact the success of the company. Responsibilities will include but not be limited to establishing the global clinical development strategy, overseeing the design and execution and reporting of clinical studies– from Phase 1 to global Phase 3/4; leading and managing a Clinical Development team with the ultimate objective of completing global regulatory submissions and approvals.

Essential Functions and Job Responsibilities:

- Manage a team of clinical development professionals responsible for designing clinical trials and executing the clinical and regulatory strategy of seldelpar for the treatment of Primary Biliary Cholangitis.

- Directly responsible for building, managing, and mentoring a clinical team. The team includes, medical monitoring, medical science, drug safety, biostatistics and data management, and other necessary functions
- Partner with Discovery, Preclinical, CMC, Medical Affairs, Commercial, etc. – on the development and refinement of the product profile and commercialization strategy of seladelpar throughout the product lifecycle
- Ensure adherence to GCP/ICH standards and internal SOPs in the conduct and reporting of clinical studies
- Responsible for the clinical development plan of seladelpar
- In conjunction with medical affairs and other team members, establish, submit and execute seladelpar presentations for external meetings as well as publications in relevant peer-reviewed journals
- Maintain responsibility for clinical sections of regulatory documents (e.g. IB, briefing documents, periodic reports)
- Ensure the smooth management and governance of external vendors involved in the design, conduct and reporting clinical trials
- Build and maintain an medical expertise in the relevant fields to maintain and foster interactions at the highest possible level with the medical and scientific communities, including key opinion leaders
- Established bridges with patients' organization to maintain and foster CymaBay image
- Work with CMO and partner with business development on the evaluation and in licensing/acquisition of external product development opportunities in alignment with CymaBay corporate goals
- Support the Company in establishing and maintaining a work environment focused on quality and fosters learning, respect, open communication, collaboration, integration, and teamwork
- Complete other tasks as assigned and agreed upon

Minimum Qualifications:

- Doctor of Medicine (M.D. or M.D. and Ph.D.)
- Minimum of 10 - 15 years of experience in the pharmaceutical or biotechnology industry
- Broad and extensive clinical development experience across all phases of product development and in multiple indications, experience in liver disease and rare orphan diseases would be pluses
- Experience in the design and conduct global clinical trial programs
- Experience in global Phase 3 program and drug registration
- Proven successful track record in leading and managing high performing teams to obtain regulatory approval in the US and the EU
- Thorough knowledge of FDA regulatory requirements, as well as knowledge of ex-US regulatory processes, and ICH/GCP guidelines are essential
- Must possess the ability to bring scientific and clinical expertise to a clinical development program and evaluate scientific and clinical strategies to obtain regulatory approval with an entrepreneurial spirit
- Proven success in executing clinical development strategies, identify core issues and obstacles for the clinical development of a designated indication and to critically evaluate outside expert advice
- Demonstrate consistent achievement of team delivery against commitments and goals
- Proven experience in managing and recruiting high performing talent

- Strategic thinker and creative problem-solver capable of identifying risks and risk mitigation strategies
- Possesses excellent teamwork, negotiation and influencing skills, able to work in a matrix project team setting and a proven track record establishing and achieving clear and consistent goals and objectives
- Excellent verbal and written communication skills
- Strong scientific writer and oral presenter