Vice President, Clinical Operations

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 clinical development for the treatment of patients with the rare liver disease primary biliary cholangitis (PBC), for the treatment of NonAlcoholic SteatoHepatitis (NASH), and for the treatment of Primary Sclerosing Cholangitis.

The Company has previously announced positive data from its Phase 2 study of seladelpar in patients with PBC and following successful discussion with the FDA and EMA has advanced into a global Phase 3 registration program. CymaBay is committed to bring this program to successful global approvals and to retain full global rights to launch and commercialize seladelpar for the treatment of PBC. In addition, the unmet medical need and the significant market size of NASH represents a unique opportunity for CymaBay, and the Company commenced a Phase 2b Proof of Concept Study in 2018 in that indication. This study was fully enrolled ahead of time and first results are expected in the third quarter of this year. Primary sclerosing cholangitis represents a third exciting opportunity for seladelpar in an additional orphan liver disease with a very high unmet medical need.

CymaBay is well funded and has the financial strength to meet its ambitious programs. For more information, please visit www.cymabay.com.

Summary:

Lead the development and implementation of clinical trial operations function. Provide oversight to clinical trial operations team to ensure clinical trials are conducted in accordance with protocols, SOPs, GCPs, and other applicable regulatory requirements. Accountable to ensure trials meet clinical study milestones according to corporate objectives. This role oversees vendor activities with appropriate risk mitigations and planning. Manage clinical operations staff, ensure staff development and manage clinical operations budget and resources to meet corporate objectives.

Essential Functions and Job Responsibilities:

- Contribute expertise in all operational activities pertaining to the execution of clinical trials (phase 1 to 4)
- Lead the operational implementation of clinical trials
- Participate in resource allocation, prioritization and budgeting to ensure department goals and milestones are aligned and meet corporate goals and timelines
- Serve as primary contact for functional area team leaders in managing protocol execution, analysis and reporting

- Comment, review and approve study documents related to trial operations (trial operational plan, monitoring plans, etc.) and other documents as appropriate to the function
- Lead operational strategy meetings to review trial status, progress, and risk assessment and management
- Analyze ongoing risk assessments with accompanying mitigation plans and contingency plans
- Create, manage and take corrective measures as necessary to keep project(s) in line with agreed timelines, quality, budget and general performance metrics
- Participate in the development and review of trial and overall clinical program budgets
- Help develop site recruitment, enrollment and engagement strategies
- Assess impact of project scope changes to understand implications on agreed plans and budgets
- Manage interdisciplinary activities to ensure clinical operations team collaborates effectively to set achievable goals, milestones and timelines
- Identify and implement best practices and process improvements, including SOP development and updating
- Ensure trial adherence to ICH, GCP and local regulations
- Maintain strong vendor interactions and collaborations, including hands-on management and interaction
- Manage and develop reporting clinical operation staff
- Complete other responsibilities as assigned

Minimum Qualifications:

- BS/MS/doctorate degree in scientific discipline or equivalent
- Minimum of 10 years of clinical operations experience in the pharmaceutical industry, including experience with pivotal studies and global registration clinical program
- Minimum of at least 5 years of direct line management experience
- Minimum of at least 5 years of successful experience in vendor management
- Thorough understanding of the process of operational execution of a clinical development trials and program (clinical trial design, implementation, management, analysis and reporting)
- Knowledge of the global drug development process and laws and regulations affecting the pharmaceutical industry
- Knowledge of the policies and processes at the FDA and other global health authorities
- Experience developing trial plans including site selection, site monitoring strategies, risk mitigation strategies, and trial budgets
- Experience managing contractors and maintaining positive vendor relationships
- Excellent written and oral communication skills with the ability to communicate clearly to all organizational levels
- Strong ability to problem-solve and diagnose the issue and implement appropriate corrective actions
- Ability to work in a fast pace environment in a collaborative manner