AVENGE BIO

Job Description – Head of Regulatory Affairs

Avenge Bio has an exciting opportunity to join the growing clinical organization as a Head of Regulatory Affairs. Reporting to the Chief Medical Officer you will be responsible for the management of regulatory activities, initially for Avenge's lead development program AVB-001. This role will be the critical interface between external vendors, regulatory agencies, and project teams. You will be responsible for developing and driving global strategies, regulatory plans, and compliance policies to align with U.S. and international requirements.

Responsibilities:

- Build and lead the Regulatory function inclusive of managing external consultants
- Responsible for directing innovative global regulatory strategies for product development and approval.
- Key focus on clinical regulatory strategy and regulatory path opportunities, and directly oversee other critical regulatory activities such as CMC
- Plan and oversee activities in support of INDs, NDAs, MAAs, CTAs and other regulatory submissions.
- Serve as the primary contact with major health authorities and liaise directly with FDA and other regulatory agencies, including the preparation and leading of agency meetings.
- Provide regulatory guidance to company personnel and project teams in all areas of regulatory affairs.
- Develop and monitor product regulatory plans including oversight of implementation of the project plan, decision making on issues that could delay project schedules or activities, communicating issues/risks to key stakeholders in a timely and consistent manner, and monitoring both functional and project performance against goals.
- Direct and assist internal staff and consultants, as required, to ensure the compliance of Avenge's drug development activities with all U.S. and international requirements.
- Perform all duties in keeping with the Company's core values, policies, and all applicable regulations.

Qualifications:

- A Bachelor of Science degree, preferably in a life science field. Masters of Science or higher preferred.
- 12+ years of regulatory strategy, managing programs in the pharmaceutical industry, including 5+ years on oncology drug development programs.
- Experience with cell/gene therapy and biologics highly preferred
- Knowledge and broad experience with regulatory procedures and regulations in multiple regions, including the US, EU, and other major health authorities.
- Significant experience leading face-to-face interactions and other formal interactions with FDA and other health authorities. Experience with Oncology division of FDA.
- Regulatory leadership and team management experience.

- Experience with CTD format and content for regulatory filings (e.g. INDs, CTAs, NDAs/BLAs, MAAs).
- Demonstrated track record in successfully progressing programs including INDs, early and late-stage development plans to completion, and in securing product approvals with successful NDAs/BLAs and/or MAAs.
- Experience with Expedited Programs such as FastTrack, Breakthrough Therapy Designation, PRIME, Orphan Drug Designation.
- Experience managing complex schedules and priorities in a dynamic environment; ability to adapt to shifting priorities, demands and timelines through excellent analytical and problem-solving capabilities.
- Strong scientific acumen and eagerness to learn.
- Ability to communicate effectively orally and in writing, both internally and with external vendors and partners.
- Familiarity with e-publishing systems for preparing regulatory submissions
- Familiarity with GCP, GMP and GLP.

About Avenge Bio, Inc.
Avenge Bio, Inc. ("Avenge") is an oncology-focused biotechnology company developing transformative cell-based immunotherapeutic products for the treatment of intractable solid tumors by incorporating its LOCOcyte™ platform. The LOCOcyte platform leverages proprietary engineered cells delivered to the local tumor environment that generate high concentrations of immune effector molecules in proximity to the tumor. This initiates a robust, local and durable systemic immune response while avoiding toxicities associated with systemic immunotherapies. Avenge's most advanced product candidate, AVB-001, produces native IL-2 immunotherapy and is initially being studied in metastatic peritoneal cancers such as ovarian cancer. Avenge has additional pipeline candidates for the treatment of a wide range of cancers including pancreatic, lung and breast cancers.

Avenge was founded in 2019 after in-licensing the exclusive license for the LOCOcyte technology from Rice University. Since inception, Avenge has raised equity from top tier investors including Longitude Capital, Blackstone (CAM Capital), Perceptive Xontogeny Venture Fund, Rock Springs Capital, and Pappas Capital. To learn more about Avenge visit www.avengebio.com.