Geneva, November 2nd, 2020

CMC – Formulation Senior Scientist

The Company

STALICLA is a clinical company developing a first-in-class precision medicine platform to accelerate drug development for patients with Neurodevelopmental Disorders (NDDs). Founded on a comprehensive understanding of the impact of NDDs on patients, their specificities and their unmet needs, STALICLA's approach starts with patients with the goal to match the right patient with the right drug. First focus of development has been Autism Spectrum Disorder (ASD). Today, patients diagnosed with NDDs account for 5-7% of births worldwide. The condition remains a high unmet medical need.

In its Geneva and Barcelona units, STALICLA has assembled a world class team of experienced drug developers and computational biologists. The company is recognized as a disruptive key player in the NDD space, using its innovative and proprietary DEPIv3 innovative systems biology AI platform.

DEPIv3 integrates multi-layered analyses of domain specific large-scale genetic, molecular, pharmacological and clinical data to generate new insights and define patient subgroups with identified precision treatments. It is the first time that such technologies have been utilized within the field of neurodevelopment with the potential to change the direction of the field.

In less than 4 years, the STALICLA platform has already proven successful in expediting and de-risking drug development for a first subgroup of patients with Autism Spectrum Disorder and identifying two additional subgroups.

STALICLA's first therapeutic package - STP1 - addresses this first distinct subgroup of ASD patients estimated to 1.5 - 2M people in the EU and North America. Clinical entry for STP1 is planned end of 2020.

STALICLA is currently scaling up DEPIv3 to advance new pipelines for additional groups of patients with NDDs.

The Role

STALICLA is currently expanding its pipeline of drug development programs and clinical activities in the US, with ongoing observational trials and interventional trial studies starting in Q4 2020.

STALICLA is therefore expanding its Team and opening a 'CMC – Formulation Senior Scientist' position. The right candidate for this role will be fully accountable for all operational aspects of CMC and formulation development studies.

As part of our Non-clinical development team, the CMC – Formulation Senior Scientist will be responsible for setting up and executing the CMC plans and formulation development for all assets from pre-clinical candidate nomination to clinical development (Phase I/II/III). S/he will work closely with the Chief Science and Innovation Officer and with the Chief Medical Officer. S/he will report to the Head of Non-clinical Development.

Primary Location: Geneva, Switzerland

Schedule: Full time

Key Responsibilities/Expertise

The candidate will be an experienced Biotech/Pharma industry professional, with a demonstrable track record in CMC and formulation development of small molecules, in the CNS therapy areas. Experience in pediatric indications is a strong asset.

Specific accountabilities include:

- Formulate, lead and drive global CMC regulatory strategy with a focus on innovation, maximizing the business benefit balanced with regulatory compliance
- Lead and implement global CMC submission activities (planning, authoring, reviewing, coordination, submission)

- Lead and manage Formulation and process development activities, including process optimization, scale up and validation in line with the overall project strategy
- Oversee the planning, design, organization and conduct of global CMC activities (including, but not limited to drug supply, synthesis optimization, formulation development, …) for Phase I/II/III clinical trials
- Ensure the delivery of CMC and formulation development activities on time and on budget
- Prepare CMC-related documentations for pre-IND and IND submissions in coordination with CROs
- Anticipate regulatory affairs matters and ensure regulatory compliance for Phase I/II/III clinical trials
- Provide input to the Target Product Profile
- Ensure that the Management Team is fully versed in CMC development issues to facilitate go / no-go decisions
- Take charge of the CMC preparation of license-out; license-in opportunities

Requirements

Basic Qualifications/Requirements:

- MSc or PhD in relevant field with significant experience in the CNS therapy area and a strong track record of success in supporting translation of small-molecule drug candidates from pre-clinical to early clinical development and/or developing a formulation allowing the optimization of a CNS drug candidate
- More than 10 years of experience being responsible for CMC and/or drug formulation development
- Minimum of 5 years of CMC regulatory experience
- Demonstrated knowledge/experience in regulatory submission and approval processes and ability to deal with CMC regulatory issues and requirements; successful experience in dealing with relevant regulatory authorities in the US and, ideally Europe
- In depth understanding of early to late-phase clinical development programs
- Hands-on experience in selecting and managing partners such as consultants, CROs and CDMOs
- Ability to both develop and implement appropriate strategies; and to identify the most efficient and cost-effective development pathway to achieve the company's objectives
- Passionate and enthusiastic about the company vision and patient needs
- Fluent in English (verbal and written communication)

In addition, the candidate is expected to have:

- Excellent problem-solving, conflict-resolution and decision-making skills
- A collaborative and patient-focused mindset
- A high comfort level working in a high paced start-up environment, where a pragmatic, resourceful, well organized and effective approach is required with limited resources
- The ability to work in a multidisciplinary and international environment
- Strong adaptation capacity to novel frameworks and work environments

STALICLA promotes diversity, equal opportunity and inclusion. Female, minority and candidates with disabilities are strongly encouraged to apply.

Please submit application to: delphine.charvin@stalicla.com and hr@stalicla.com