Geneva, August 18th, 2020

Head of Non-Clinical Development

The Company

STALICLA is a near 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 personalized 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 specialty.

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 in 2020.

To support its platform and pipeline development, STALICLA has developed a network of top tier research and clinical partners in the US.

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 2020.

STALICLA, is therefore, expanding its Team and opening a 'Head of Non-Clinical Development' position to reinforce its Drug Development Team and ensure the efficient and smooth execution of clinical-enabling studies. The right candidate for this role will be fully accountable for all operational aspects of nonclinical studies.

The Head of Non-Clinical Development will be responsible for setting up and executing the plans for all assets from pre-clinical candidate nomination into (early) clinical development and for ensuring a high-quality drug development pipeline. S/he will lead a small, highly efficient and effective internal development team and continue to work with the internal functions and with external CROs, consultants and KOLs. The Head of Non-Clinical Development will work closely with the Chief Medical Officer and the Chief Science and Innovation Officer to ensure effective clinical trial strategy, pipeline expansion, design and execution of development plan. S/he will report to the CEO.

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 non-clinical development of small molecules, in the CNS therapy areas, and in preparation of regulatory dossier to enable First-In-Human studies (including IND). Experience in paediatric indications is a plus.

Specific accountabilities include:

- Ensure the delivery of nonclinical development activities on time and on budget, and be responsible for the preparation and coverage of relevant safety, toxicology, bioanalytics and CMC aspects
- Ensure that the company is accessing valuable expertise through external networks where appropriate, managing nonclinical studies and fostering effective, long term relationships with appropriate KOLs, contracted CROs and CDMOs
- Prepare pre-IND and IND submissions in coordination with CROs
- Anticipate regulatory affairs matters and ensure regulatory compliance for Phase I/II clinical trials
- Provide hands-on management and supervision of the ongoing interactions towards regulatory filings at European and US authorities
- Provide nonclinical input to the Target Product Profile and ensure assessment of the clinical benefit – risk profile during development
- Oversee the planning, design, organization and conduct of Phase I/II clinical trials and provide input into the clinical proof of concept / proof of mechanism trial design
- Build and manage over time a highly efficient and effective small internal development team as the company grows and evolves
- Ensure that the Management Team is fully versed in development issues to facilitate go / no-go decisions
- Represent the nonclinical development perspective where needed in investor presentations and with business and financial partners and in the company's dealings with regulatory authorities
- Has ample experience leading teams in particular through NCD, Phase I & Phase II trials
- Other duties, as they arise

The Head of Nonclinical Development oversees document preparation:

- Leads and participates in generating the Nonclinical Development Plan
- Prepares and reviews the documents to support meeting requests and briefing packages for meetings with Regulatory agencies
- Writes the nonclinical section of the Investigator Brochure and Regulatory dossier
- Prepares answers to questions from Regulatory Agencies on the nonclinical safety, tolerability, efficacy of the project/product
- Takes charge of the nonclinical preparation of license-out; license-in opportunities

Requirements

Basic Qualifications/Requirements:

- PhD in relevant field (chemistry is a plus) with significant experience in the CNS therapy area and a strong track record of success in translating small-molecule drug candidates from pre-clinical to early clinical development
- More than 10 years of experience being responsible for drug development, at the transition between pre-clinical research and clinical development
- A demonstrable track record of having successfully moved drug candidates forward from pre-clinical through to early clinical development with good experience in clinical operations management and in the management of outsourced clinical research activities as well as managing an internal drug development team
- Solid understanding and knowledge of safety, toxicology, bioanalytics and CMC aspects with regard to the design and execution of Phase I – II clinical trials
- Hands-on experience in selecting and managing partners such as consultants, CROs and CDMOs
- Successful experience in dealing with relevant regulatory authorities in the US and, ideally Europe
- Well-developed strategic thinking skills combined with hands-on execution, maintaining close control and having a key operational role with clinical trials;
- Sound understanding of clinical and regulatory pathways for drug development, and of the potential needs of (development) partners; able 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 the patient needs

Preferred Qualifications/Capacity:

- Clinical research or pharmaceutical experience in CNS disorder, with in depth understanding of early to late-phase clinical development programs
- Strong networking ability
- Strong interpersonal, communication, presentation, and negotiation skills across all levels of the organization
- Performance oriented with ability to work along agreed timelines
- Outstanding communicator. Excellent problem-solving, conflict-resolution and decision-making skills
- Fluent in English (verbal and written communication)
- Able and willing to travel as the role requires

In addition, the candidate is expected to have:

- 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
- A passionate, energetic and enthusiastic personality that will ensure commitment to the company and its vision
- The ability to work in a multidisciplinary and international environment
- Strong adaptation capacity to novel frameworks and work environments

Female and minority candidates are encouraged to apply.

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