Geneva, November 2nd, 2020

Biomarker – Companion Diagnostics 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 'Biomarker – Companion Diagnostics Senior Scientist' position. The right candidate for this role will be fully accountable for all operational aspects of biomarkers and companion diagnostics development studies.

As part of our Non-clinical development team, the Biomarker – Companion Diagnostics Senior Scientist will be responsible for the delivery of biomarker strategies translating from preclinical through early stage of clinical development. In addition, s/he will coordinate development and validation of biomarker assays and companion diagnostics in order to provide tools for compound evaluation and patient stratification throughout the phases of drug development. 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 biomarker and companion diagnostics development. Experience in the CNS therapy areas is a strong asset.

Specific accountabilities include:

- Develop and implement effective biomarker and diagnostic strategies for our projects across early and late phases clinical development
- Provide expert biomarker and diagnostic input to the design, implementation, analysis and reporting of studies including supporting the preparation of protocols and regulatory documents

- Ensure scientific quality, appropriate experimental design of biomarkers studies and guide interpretation of results
- Lead the implementation of biomarker activities in clinical studies
- Implement and apply innovative biomarker solution and companion diagnostic tests to our projects
- Anticipate regulatory affairs matters and ensure regulatory compliance for Phase I/II/III clinical trials

Requirements

Basic Qualifications/Requirements:

- MSc or PhD in relevant field and a strong track record of success in developing biomarkers supporting the clinical development of drug candidates and/or developing companion diagnostics
- More than 10 years of experience being responsible for biomarker and/or companion diagnostics development
- Demonstrated knowledge/experience in regulatory submission and approval processes and ability to deal with regulatory issues and requirements relevant to biomarker and companion diagnostics development; successful experience in dealing with relevant regulatory authorities in the US and, ideally Europe
- Proven track record of implementing biomarker strategy in clinical trials
- Experience of delivering companion diagnostics and regulatory interactions. Experience of commercialization is a plus
- 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 encouraged to apply.

Please submit application to: hr@stalicla.com