Geneva, March 1st, 2021

Biomarker – Companion Diagnostics Senior Scientist

The Company

STALICLA is a patient-centric clinical-stage company on a unique mission to identify, develop and bring precision medicine to patients with neurodevelopmental disorders (NDD). Overall, neurodevelopmental disorders are disabilities in the functioning of the brain that affect a child's behavior, memory or ability to learn e.g. intellectual disability, dyslexia, attention deficit hyperactivity disorder (ADHD), learning deficits and autism. NDDs affect 1 in 6 children worldwide.

STALICLA's first focus of development has been Autism Spectrum Disorder (ASD). Today, patients diagnosed with ASD account for 1-1.5% of the world population. The condition remains a high unmet medical need.

STALICLA has assembled a world-class team of experienced drug developers, clinicians and computational systems biologists, geneticists and software engineers, developing a first in class precision medicine platform using systems biology, machine learning & statistical modeling to accelerate drug development for patients with NDDs. DEPI, the company's unique drug discovery platform, characterizes biologically similar subgroups of patients within highly variable populations of patients with neurodevelopmental disorders, and further identifies tailored treatments. To support its drug discovery platform and pipeline development, STALICLA has established strong networks within top tier research and clinical centers.

STALICLA's platform has already proven successful in expediting and de-risking a first pipeline, STP1, tailored to a subgroup of patients with autism spectrum disorder which will be entering clinical trials this year. In addition, STALICLA is currently advancing new precision medicine pipelines for two additional groups of patients with ASD.

The Role

As rapidly growing company, STALICLA is currently expanding its team and is opening – for immediate entry – a Biomarker – Companion Diagnostics Senior Scientist position. He/She will be part of the STALICLA Leadership Team, supporting Companion Diagnostic teams by

providing evaluation, strategy, development, and implementation of diagnostic tests in support STALICLA clinical portfolio.

He/She will be responsible for end-to-end diagnostic strategy in collaboration with key stakeholders and ensure that the diagnostic strategy is in alignment with the compound strategy and with timelines for registration of the therapeutic drug product. You will ensure the timely implementation of diagnostic strategy for the appropriate clinical programs while working in a highly matrixed environment across functional units within Genmab and external Diagnostic companies.

Responsibilities include but are not limited to:

- Represent Diagnostics Team on select translational research teams and compound development teams in enabling personalized healthcare for therapeutic programs ;
- Collaborate with key stakeholders, including, but not limited to, Discovery, Translational Research, Clinical Research, Regulatory and Commercial groups to develop a diagnostic strategy to enable registration of a pharmaceutical asset alongside a diagnostic product ;
- Interact with Discovery and Clinical groups to understand the predictive hypotheses to be tested for specific programs. Collaborate with internal research capabilities to develop, validate, and implement a predictive assay if not already available. Working closely with discovery, clinical and biomarker operations team to select contract laboratory for testing predictive assays in early clinical development. Help oversee assay transfer to contract laboratory and ensure proper assay validation by working with subject matter experts within the department ;
- Understand CLIA-laboratory, FDA testing guidelines and assay validation requirements ;
- Collaborate with Discovery and Clinical Research to design studies to test the clinical utility of the companion diagnostic ;
- Help to select the diagnostic partner to deliver potential companion diagnostic kit in time for pharmaceutical registration ;
- Work with colleagues in Regulatory Groups to ensure that all relevant regulatory documents (e.g. IDEs, PMAs, etc.) are delivered and communicate with regulatory authorities when required ;
- Regularly communicates updates to, and seeks feedback from, Clinical Teams, Compound Development Teams, and other stakeholders where appropriate, surrounding progress of the companion diagnostic program ;
- Keep current with novel technologies that have impact on oncology diagnostic testing. Aid in selection of diagnostic assay methodologies. Help map marketplace on optimal technologies/platforms and use strategic considerations in choosing a diagnostic partner ;
- Lead the development of single-plex/multiplex assays, including novel technologies,

to support investigational and approved products in collaboration with diagnostic partners ;
- Coordinate all executable activities between development teams and external diagnostic partners ensuring alignment of companion diagnostic development milestones with clinical milestones by developing/tracking timelines, budgets, and resources towards ensuring delivery of critical milestones from diagnostic partner and provides timely updates to relevant functional teams regarding development status ;
- Provide internal and external subject matter expertise for precision medicine activities by acquiring and disseminating precision medicine knowledge to key stakeholders.

Requirements:

- C2 level or native English mandatory ;
- PhD (preferred) in Life Science or equivalent M.S. degree will be considered for exceptional candidates;
- At least five years of experience in assay and In Vitro Diagnostic Regulations, with broad understanding of design control process, analytical and clinical validation, manufacturing, GCP, GLP, and GMP requirements, US and global regulatory submissions (Pre-Subs, IDE, PMA), and commercialization of diagnostics;
- Demonstrated matrix leadership skills and ability to work effectively across multiple disciplines internal and external to the organization, with a track-record of successfully managed Diagnostic projects and success in working with multiple cross-functional teams;
- Broad knowledge and understanding of established and novel assay technologies (e.g., IHC, digital pathology, PCR, NGS, liquid biopsy, imaging);
- Broad knowledge of the drug development process (clinical trials, efficacy endpoints, biomarker testing);
- Excellent communication both orally and written;
- Respectful of deadlines;
- Proficiency in all of Microsoft Office;
- Hard working, driven to achieve creative and sound results.

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