STALICLA

STALICLA publishes on first precision medicine study in autism

Geneva, Switzerland, May 8, 2024 – STALICLA SA, a Swiss neuro precision biotech company, has provided proof-of-concept clinical data for DEPI (Databased Endophenotyping Patient Identification), its neuro precision discovery platform, enabling the identification of biological subgroups of patients with Autism Spectrum Disorder (ASD) and matching treatments, in a study published last week in Biomedicines (https://www.mdpi.com/2227-9059/12/5/991).

Lynn Durham, CEO of STALICLA said: "This newly published study supports the development of our lead neurodevelopment product, STP1, using DEPI, to identify individuals most likely to benefit from our treatment. This study demonstrates the application of a precision medicine approach that can change the paradigm of ASD treatment, where specific, non-behavioral clinical signs and symptoms that can be observed in patients in the clinic, mirror biological differences."

Application of a DEPI-generated medical questionnaire led to confirmation that about one quarter of screened individuals matched the clinical criteria of ASD-Phen1, confirming DEPI predictions (~24% of ASD individuals).

Blood analyses confirmed the existence of specific biological alterations (metabolic and transcriptomic) differentiating patients with ASD-Phen1 from the general autism population and control subjects without autism. Finally, STALICLA's STP1 drug combination was shown to revert the observed molecular alterations in patients with ASD-Phen1 in vitro, in patient-derived cell lines.

Laura Perez-Cano, Head of Discovery at STALICLA said: "Autism spectrum disorder (ASD) diagnosis has historically been defined using behavioral criteria, overlooking genetic, physiological and clinical patient profiles. This "one-size-fits-all" has limited the ASD drug development landscape and, as a result, candidate treatments have failed in clinical trials. We are now re-syndromizing patients with complex forms of ASD to enable the development of precision medicine-based treatment options."

Since the Greenwood study in 2019, STALICLA has replicated these findings in an independent study conducted at Cincinnati Children's Hospital and identified two patient subgroups, ASD-Phen1 (~20% of ASD population) and ASD-Phen2 (~15% of the ASD population) with their corresponding clinical signs and symptoms and matching treatments, STP1 and STP2. The company has also conducted an interventional phase 1b study establishing good safety and tolerability, strong dose-related target engagement and strong correlation between dosage and improvement of autism severity standardized scores (ABC, SRS) with a manuscript currently under review.

STALICLA SA is a Swiss clinical-stage biopharmaceutical company, pioneering precision treatment in neurodevelopmental and neuropsychiatric disorders. Its AI-driven precision neuro medicine platform has allowed to identify two precision small molecule drug candidates for autism spectrum disorder, STP1 and STP2, both planned to enter Phase 2 trials in 2024. Following the in-licensing of Mavoglurant from Novartis in 2023, STALICLA has also established an advanced mGluR5 NAM platform offering multi-faceted late-stage clinical development opportunities broadening STALICLA's scope to address wider CNS disease unmet needs. For more information, please visit: www.stalicla.com.

For further information, please contact:
Lynn Durham, Founder & CEO
lynn.durham@stalicla.com