STALICLA

Press Release

STALICLA publishes pioneering phase 1b data on precision treatment for autism spectrum disorder in *Biomedicines*

STALICLA's precision psychiatry study highlights strong EEG-based target engagement of STP1 treatment in defined subgroup of patients with autism and numerical improvement in core symptoms

Geneva, Switzerland – June 27, 2024 – STALICLA SA, a Swiss neuro precision biotech company dedicated to developing precision medicine-based treatments for neuropsychiatric and neurodevelopmental disorders, today announced the publication of a landmark phase 1b study with STP1, a novel combination therapy tailored for the treatment of a clinically and biologically defined subgroup of patients with autism spectrum disorder (ASD), named ASD Phenotype 1 (ASD-Phen1).

The results of the study were published in the peer-reviewed journal *Biomedicines*, in an article titled "Safety, Tolerability, and EEG-Based Target Engagement of STP1 (PDE3,4 Inhibitor and NKCC1 Antagonist) in a Randomized Clinical Trial in a Subgroup of Patients with ASD".

Lynn Durham, CEO of STALICLA, highlighted: "This study marks a significant milestone in the advancement of precision medicine for ASD. It is a first-of-its-kind stratification-based approach for clinical development in neurodevelopmental disorders, demonstrating the potential of precision medicine in ASD."

The randomized, double-blind, placebo-controlled **phase 1b clinical trial** evaluated the safety and tolerability of STP1, a combination of ibudilast and bumetanide, in ASD-Phen1 patients. The clinical trial (registered at clinicaltrials.gov NCT04644003), involved two 14-day treatment phases of ASD-Phen1 patients receiving STP1 or placebo.

The results showed that STP1 was well-tolerated with **no significant adverse effects** reported. **Significant and dose-related reductions in gamma power** were observed in the whole brains of patients taking STP1, particularly in regions associated with executive function and memory. Additionally, STP1 increased alpha 2 power in frontal and occipital regions, while improving habituation and neural synchronization to auditory chirps.

Dr. Craig A. Erickson, Associate Professor, UC Department of Psychiatry and Behavioral Neuroscience, Cincinnati Children's Hospital Medical Center, and the principal investigator of the study, remarked: "The electrophysiological signals from this study are remarkable and represent the strongest early trial target engagement signals our lab has seen in the autism field."

Dr. Laura Pérez-Cano, Head of Discovery at STALICLA and co-author of the study, added: "These findings not only highlight the potential of STP1 as a therapeutic option for ASD-Phen1 patients but also underscore the importance of combining biologically-based patient stratification with quantifiable outcome measures such as EEG that can then be correlated with behavioral measures."

By focusing on a biologically defined subgroup of ASD patients, STALICLA is moving closer to making personalized treatment options a reality for patients with ASD. This approach has the potential to revolutionize the treatment of ASD and other neuropsychiatric conditions.

For the full article in *Biomedicines* click **here**.

About STALICLA:
STALICLA is a global, clinical-stage biotechnology company focused on advancing precision medicine for brain disorders.

The company has developed a unique neuro precision development platform, DEPI, supported by clinical validation in a first indication: Autism Spectrum Disorder. Its lead neurodevelopmental disorder asset, STP1, is entering Phase 2 trials.

Its lead neuropsychiatry asset, STP7 (Mavoglurant), fully funded by the US government, will soon be Phase 3 ready for Cocaine Use Disorder.

For more information, please visit: **www.stalicla.com**.

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