PRESS RELEASE

STALICLA initiates U.S. Phase 3 enabling DDI study of STP7 (Mavoglurant) to treat cocaine use disorder

Geneva, Switzerland, May 2, 2024 – STALICLA SA, a late-stage biotechnology company specializing in precision medicine for brain disorders, announces the First Patient First Visit (FPFV) for the company's drug-drug interaction (DDI) study of STP7 (Mavoglurant), an mGluR5 negative allosteric modulator, licensed to STALICLA by Novartis. The DDI study is the last regulatory requirement in a comprehensive Phase 2 program and completion is expected to trigger initiation of a Phase 3 study in the U.S. in 2025.

Lynn Durham, CEO and Founder of STALICLA said, "This DDI study unlocks the opportunity under our Cooperative Research and Development Agreement with the U.S. NIH National Institute of Drug Abuse (NIDA) to begin Phase 3 trials for STP7 in 2025 to address the high unmet medical need of cocaine abuse globally. Results from successfully completed Phase 2 studies for cocaine use disorder (CUD) showed highly convincing and unprecedented efficacy results including increase in abstinence from cocaine use and reduction in co-morbid dependencies such as alcohol abuse with STP7 (Mavoglurant). In addition, STALICLA is investigating alternative therapeutic indications for STP7 (Mavoglurant) to benefit patients with other CNS conditions."

STP7 (Mavoglurant) is the most clinically advanced negative allosteric modulator of the glutamate receptor 5 (mGluR5 NAM). As well as its role in addiction pathophysiology, mGluR5 has been implicated in mood disorders and neurodevelopmental disorders such as Fragile X and autism spectrum disorder. Comprehensive clinical studies by Novartis of STP7 (Mavoglurant) to date have included over 1800 adults for up to 2 years, demonstrating good safety and tolerability and significant reduction in cocaine use and positioning STP7 (Mavoglurant) as a strong candidate therapy for substance use and other CNS disorders.

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.

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