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MAPLIGHT THERAPEUTICS ANNOUNCES COMPLETION OF DOSING IN PHASE 1 STUDY OF THERAPY FOR SOCIAL DEFICIT IN AUTISM SPECTRUM DISORDER

Interim data from Phase 1 clinical trial with repeated dosing in healthy volunteers demonstrates positive safety and tolerability profile for ML-004

SAN FRANCISCO, November 23, 2020 - MapLight Therapeutics today announced it has completed dosing of healthy volunteers across five cohorts in a Phase 1 clinical trial evaluating the safety of ML-004, a selective serotonin receptor agonist. Based on results from the study to date, ML-004, which MapLight intends to evaluate for the treatment of deficits in sociability and irritability seen in individuals with autism spectrum disorder (ASD), appears to be well tolerated at all dose levels evaluated.

“The completion of dosing in the company’s first Phase 1 trial is an important milestone for MapLight Therapeutics,” stated Christopher Kroeger, M.D., MBA, Chief Executive Officer and Founder. “The data collected in this trial to date support the safety and tolerability of sustained dosing at levels well above what we predict will be required to treat patients with ASD. MapLight is excited to announce the completion of this initial step in developing what it hopes may be the first approved drug to treat social deficit in these patients.”

The Phase 1 clinical trial is a double-blinded safety study assessing plasma and CSF pharmacokinetics (CSF PK). Forty healthy volunteers across five patient cohorts were enrolled. Preliminary data show no safety concerns and limited adverse events (AEs), all of which were tolerated and resolved. CSF PK analysis confirms adequate brain exposure and that the therapeutic target concentration was achieved at a well-tolerated dose. MapLight is eager to move forward and test the pharmacokinetics of a modified release formulation of ML-004 in a future trial to support once-a-day dosing.

“My observation is that the dosing regimen has been tolerated better than expected with limited AEs and no safety concerns,” stated Jason Lickliter of Nucleus Network, who is the primary investigator in the trial. “We look forward to reviewing the final data from the Phase 1 clinical trial when it is available.”

About ML-004
ML-004 is MapLight's lead clinical compound. Its selective pharmacological properties of make it a highly specific therapy with limited side effects. The company is developing ML-004 for multiple indications, including sociability and irritability in ASD and agitation and aggression in Alzheimer's Disease.

About MapLight Therapeutics
MapLight Therapeutics is a biopharmaceutical company that discovers and develops novel therapeutics for patients with disorders of the central nervous system (CNS). MapLight's mission is to address the critical unmet medical needs of these patients by developing innovative, targeted therapies to treat the defining clinical manifestations of their disease. The company's circuit-based approach and proprietary discovery platform is designed to bring more effective and safer treatments to these patients by rationally developing therapies that target defective brain circuits. The company's platform, which includes STARmap (three-dimensional spatial transcriptomics) and optogenetics, enables the identification of circuit-specific targets and validation that target modulation ameliorates disease. Learn more at www.maplightrx.com.

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