MapLight Therapeutics Announces Initiation of Phase 2 Trial of Novel M1/M4 Muscarinic Agonist ML-007C-MA for the Treatment of Alzheimer's Disease Psychosis

Sep 17, 2025

SAN FRANCISCO AND BOSTON, SEPTEMBER 17, 2025 – MapLight Therapeutics today announced the initiation of a Phase 2 study to evaluate the efficacy, safety and tolerability of ML-007C-MA, an investigational novel M1/M4 agonist, as a potential treatment for Alzheimer's disease psychosis (ADP). The Phase 2 VISTA study has been designed based on the results of an extensive Phase 1 development program that included 270 healthy volunteers, including 42 healthy elderly volunteers who received active drug.

"There are no FDA-approved treatments for ADP and off-label use of antipsychotics with marginal efficacy and significant safety concerns can lead to poor patient outcomes," said Christopher Kroeger, M.D., M.B.A., Chief Executive Officer and Founder of MapLight. "Muscarinic receptor agonism has shown promising results as a therapeutic strategy for ADP, and the initiation of the VISTA study marks an important milestone as we pursue parallel development of ML-007C-MA in schizophrenia, ADP, and potentially other neuropsychiatric conditions."

The Phase 2 VISTA study is a randomized, double-blind, placebo-controlled trial evaluating a twice-daily dose of ML-007C-MA for the treatment of hallucinations and delusions associated with ADP. This global study is expected to enroll approximately 300 patients. The primary endpoint of the study is the change in the Neuropsychiatric Inventory – Clinician Rating Scale Hallucinations and Delusions, or NPI-C H+D, score from baseline to Week 7.

"ML-007C-MA is well positioned as a potential treatment for ADP based on the favorable safety and tolerability profile observed in healthy elderly volunteers in Phase 1 whose CNS exposures achieved or exceeded levels that we anticipate being clinically relevant," said Erin Foff, M.D., Ph.D., Chief Medical Officer of MapLight.

For more information about this study, visit: ClinicalTrials.gov (NCT06887192).

Learn more at www.maplightrx.com

For investor inquiries: investors@maplightrx.com

For media inquiries: media@maplightrx.com

About ML-007C-MA

ML-007C-MA, also referred to as ML-007C/PAC, is an oral, extended-release, fixed-dose combination of the investigational M1/M4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic (PAC). ML-007C-MA is designed to activate both M1 and M4 muscarinic receptors in the central nervous system to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects. ML-007C-MA offers the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding CSF exposures expected to result in improvement across key symptom domains.

About Alzheimer's Disease Psychosis (ADP)

ADP is a serious and common neuropsychiatric complication of Alzheimer's disease (AD), characterized by the presence of delusions and/or hallucinations. Psychotic symptoms occur in approximately 40% of individuals with AD at some point throughout the course of their illness, and the likelihood of developing these symptoms increases as the disease progresses. ADP is associated with significantly poorer outcomes, including faster cognitive and functional decline, higher rates of institutionalization, and increased mortality.

About MapLight

MapLight Therapeutics is a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system disorders. The company was founded by globally recognized leaders in psychiatry and neuroscience research to address the lack of circuit-specific pharmacotherapies available for patients. MapLight's discovery platform holds the potential to fill this void by identifying neural circuits causally linked to disease and targeting those circuits for therapeutic modulation.