# MAPLIGHT THERAPEUTICS ANNOUNCES INITIATION OF PHASE 1 CLINICAL TRIAL FOR ML-007/PAC, UNDER DEVELOPMENT FOR SCHIZOPHRENIA AND ALZHEIMER'S DISEASE PSYCHOSIS

- *Study to evaluate safety and tolerability of extended-release fixed dose combination ML-007/PAC with precision-matched release kinetics in advance of planned Phase 2 clinical trials*

- *ML-007/PAC dosing regimens to be assessed in healthy non-elderly and elderly adults*

**SAN FRANCISCO AND BOSTON, MARCH 28, 2024** - MapLight Therapeutics, a clinical-stage biopharmaceutical company working to develop targeted novel therapeutics to improve the lives of patients suffering from debilitating CNS disorders, today announced initiation of a Phase 1 clinical trial evaluating ML-007/PAC, MapLight's extended-release fixed-dose combination formulation of the novel, investigational muscarinic agonist ML-007 and a precision-matched peripherally active anticholinergic (PAC). This trial builds upon findings from three prior Phase 1 clinical trials evaluating safety and tolerability of ML-007 co-administered with the PAC.

This four-cohort trial will evaluate the safety, tolerability and pharmacokinetics (PK) of several dose strengths of ML-007/PAC in healthy non-elderly and elderly adults.

"We are pleased with the continued progress of our ML-007 clinical development program," stated Christopher Kroeger, M.D., MBA, Chief Executive Officer and Founder. "We have already evaluated the safety and tolerability profile of ML-007 dosed alone or with the PAC in three clinical trials and observed favorable tolerability results in adults, including in elderly subjects. Data from this fourth Phase 1 trial will inform the ML-007/PAC dosing regimen to bring forward into our planned Phase 2 trials in schizophrenia and Alzheimer's disease psychosis. We look forward to initiating our first Phase 2 trial of ML-007/PAC in schizophrenia later this year."

"There still remains a profound level of unmet need in the treatment of schizophrenia with about 60% of patients having only a partial response or no response to treatment," said John Kane M.D., Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. "The clinical trial evidence for muscarinic receptor agents has been very encouraging, and I believe this new class of agents has the potential to improve the overall treatment of schizophrenia."

**About ML-007**

ML-007 is an investigational, CNS-penetrant muscarinic receptor agonist designed to target $M_1$ and $M_4$ muscarinic receptor subtypes with no direct activity on dopamine receptors. Deficits in $M_1$ receptors are linked to schizophrenia, and $M_1$ receptors directly regulate neural circuits known to be important in both psychosis and cognition. $M_4$ receptors regulate a complementary neural circuit known to be important in psychosis.

**About ML-007/PAC**

ML-007/PAC, also referred to as ML-007C-MA, is an extended-release fixed-dose combination of the investigational, $M_1/M_4$ muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic (PAC). ML-007/PAC was specifically designed to unlock the full potential of ML-007 by pairing it with a precision-matched anticholinergic and to optimize pharmacokinetic

synchronization of its agonist and antagonist components, without sacrificing activation of both $M_1$ and $M_4$ receptors.

**About Schizophrenia**
Schizophrenia is a serious, debilitating mental illness characterized by disturbances in perception, thinking, emotional reaction, and behavior. Schizophrenia can cause people to interpret reality abnormally and includes a combination of positive, negative, and cognitive symptoms. Approximately 60% of people with schizophrenia have no response or only a partial response to the available standard of care treatments, leaving a substantial portion of the population with urgent unmet needs.

**About Alzheimer's Disease Psychosis**
Approximately 40% of people in the United States who are diagnosed with Alzheimer's disease (AD) also experience symptoms of psychosis. These symptoms are associated with a worsened prognosis and are predictive of earlier progression to nursing home care, severe dementia and death. Despite the severity of the condition, there are no therapies approved by the FDA for the treatment of AD psychosis.

**About MapLight Therapeutics**
MapLight is a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system, or CNS, disorders. MapLight 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. Learn more at www.maplightrx.com.

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