MapLight Therapeutics Announces Initiation of Phase 2 Trial of Its Novel M_1/M_4 Muscarinic Agonist ML-007C-MA for the Treatment of Schizophrenia

REDWOOD CITY, JULY 07, 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 M_1/M_4 agonist, as a potential treatment for schizophrenia. The Phase 2 ZEPHYR study has been designed based on the results of an extensive Phase 1 development program that included 270 healthy volunteers.

“There is a significant need for new and innovative medicines for the treatment of schizophrenia, a disorder that impacts over 20 million people worldwide,” said Christopher Kroeger, M.D., M.B.A., Chief Executive Officer and Founder of MapLight. “We are encouraged by the potential of muscarinic agonists to address the full spectrum of schizophrenia symptoms and remain committed to advancing ML-007C-MA to help meet the urgent needs of these patients.”

The Phase 2 ZEPHYR study is a randomized, double-blind, placebo-controlled trial evaluating once- and twice-daily doses of ML-007C-MA in adults with a primary diagnosis of schizophrenia who are experiencing an acute exacerbation or relapse of symptoms. The study is expected to enroll approximately 300 patients throughout the United States. The primary endpoint of the study is the change in the Positive and Negative Syndrome Scale (PANSS) total score from baseline to Week 5.

“We are encouraged by the differentiated profile demonstrated by ML-007C-MA in Phase 1 studies, which included favorable safety and tolerability results with once- and twice-daily dosing, minimal titration requirements and no need for fasting, while achieving CSF exposures expected to be clinically relevant,” said Erin Foff, M.D., Ph.D., Chief Medical Officer of MapLight. “This Phase 2 study is designed to be adequately sized and well controlled to evaluate the efficacy, safety and tolerability profile at the doses selected.”

For more information about this study, visit: ClinicalTrials.gov (NCT07038876).

About ML-007/PAC

ML-007C-MA, also referred to as ML-007C/PAC, is an oral, extended-release, fixed-dose combination of the investigational M_1/M_4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic (PAC). Potential differentiation for ML-007C-MA is driven by an optimized pharmacokinetic synchronization of its agonist and antagonist components in the periphery, without sacrificing strong activation of both M_1 and M_4 receptors in the central nervous system.

About Schizophrenia

Schizophrenia is a complex psychiatric disorder characterized by a range of symptoms that include positive symptoms of hallucinations, delusions, and disorganized thinking; negative symptoms of social withdrawal, decreased emotional expression, anhedonia, and apathy; and cognitive impairment, all of which are major drivers of disability due to significant impairment of social and occupational functioning. Schizophrenia is widely recognized as a chronic and debilitating condition, affecting approximately 3 million people in the US and 20 million globally. Schizophrenia remains one of the leading causes of disability and is associated with an increased risk for premature 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.

Learn more at www.maplightrx.com.

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