MapLight Therapeutics Receives Fast Track Designation for ML-007C-MA for Alzheimer's Disease Psychosis

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SAN FRANCISCO and BOSTON, Jan. 05, 2026 (GLOBE NEWSWIRE) -- MapLight Therapeutics, Inc. ("MapLight") (Nasdaq: MPLT) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ML-007C-MA, an investigational novel M_1/M_4 muscarinic agonist, for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis (ADP).

The Fast Track process is intended to facilitate the development and expedite the review of investigational therapies for serious conditions with unmet medical need. A drug with Fast Track designation may be eligible for more frequent interactions with the FDA, as well as accelerated approval and priority review, if applicable criteria are met.

"FDA's Fast Track designation underscores the significant unmet need of the millions of people with Alzheimer's disease psychosis with no currently approved treatment options," said Erin Foff, M.D., Ph.D., Chief Medical Officer of MapLight. "This designation is an important milestone for the ML-007C-MA program that recognizes its potential to address the psychotic symptoms that frequently accompany the cognitive decline in people living with Alzheimer's disease. We remain committed to working closely with the FDA to advance this program expeditiously through our ongoing Phase 2 VISTA study."

In a Phase 1 clinical trial, ML-007C-MA demonstrated a generally favorable safety and tolerability profile with twice daily dosing in healthy elderly participants. Enrollment is currently ongoing in the Phase 2 VISTA study, a randomized, double-blind, placebo-controlled trial evaluating ML-007C-MA for the treatment of hallucinations and delusions associated with ADP. MapLight expects to enroll 300 participants in the trial and report topline results in the second half of 2027.

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 M_1/M_4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic (PAC). ML-007C-MA is designed to activate both M_1 and M_4 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 Therapeutics

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. The company'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.

For more information, please visit www.maplightrx.com.

Forward Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including the Company's expectations regarding the potential benefits of its current and future product candidates and programs, plans for its current and future clinical trials, the anticipated timing of results from the Company's clinical trials and the potential benefits of Fast Track designation. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, are intended to identify forward-looking statements. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the Company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in the Company's filings with the U.S. Securities and Exchange Commission (SEC)), many of which are beyond the Company's control and subject to change. Actual results could be materially different. Risks and uncertainties include: global macroeconomic conditions and related volatility; expectations regarding the initiation, progress, and expected results of the Company's preclinical studies, clinical trials and research and development programs; the unpredictable relationship between preclinical study results and clinical study results; the risk that results obtained in any clinical trials to date may not be indicative of results obtained in ongoing or future trials; the timing or likelihood of regulatory filings and approvals; expectations regarding the Company's ability to fund its current operations; and other risks and uncertainties identified in the Company's Quarterly Report on Form 10-Q filed with the SEC on December 4, 2025, and subsequent disclosure documents the Company may file with the SEC. The Company claims the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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